UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters Products Liability Litigation	**MD-15-02641-PHX-DGC**
	Phoenix, Arizona
	May 24, 2018
Doris Jones, an individual,	
Plaintiff,	
v.	CV-16-00782-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,	
Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 7 - A.M. SESSION

(Pages 1348 - 1483)

Official Court Reporter:
Patricia Lyons, RMR, CRR
Sandra Day O'Connor U.S. Courthouse, Ste. 312
401 West Washington Street, SPC 41
Phoenix, Arizona 85003-2150
(602) 322-7257

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared with Computer-Aided Transcription

A P P E A R A N C E S

For Plaintiff:

Gallagher & Kennedy
By: **MARK S. O'CONNOR**, ESQ.
By: **PAUL L. STOLLER**, ESQ.
By: **SHANNON L. CLARK**, ESQ.
By: **C. LINCOLN COMBS**, ESQ.
2575 East Camelback Road, Suite 1100
Phoenix, AZ 85016

Lopez McHugh, LLP
By: **RAMON ROSSI LOPEZ**, ESQ.
100 Bayview Circle, Suite 5600
Newport Beach, CA 92660

Lopez McHugh, LLP
By: **JOSHUA MANKOFF**, ESQ.
214 Flynn Ave.
Moorestown, NJ 08057

Heaviside Reed Zaic
By: **JULIA REED ZAIC**, ESQ.
By: **LAURA E. SMITH**, ESQ.
312 Broadway, Ste. 203
Laguna Beach, CA 92651

For Defendants:

Nelson Mullins Riley & Scarborough
By: **RICHARD B. NORTH, JR.** ESQ.
By: **ELIZABETH C. HELM**, ESQ.
201 17th Street NW, Suite 1700
Atlanta, GA 30363

Nelson Mullins Riley & Scarborough.
BY: **JAMES F. ROGERS**, ESQ.
1320 Main St.
Columbia, SC 29201

Snell & Wilmer
By: **AMANDA C. SHERIDAN**, ESQ.
400 East Van Buren
Phoenix, AZ 85004

EXAMINATION

WITNESS		PAGE
DR. DONNA-BEA TILLMAN		
	Direct Examination (Cont'd) By Mr. North	23
	Cross-Examination By Mr. Lopez	93

EXHIBITS

NUMBER	DESCRIPTION	PAGE
6075	Nov. 10, 2004 FDA Internal Memo re Dear Doctor Letter	44
6064	July 26, 2005 Internal FDA memo re BPV Responses to FDA AI re Modified Recovery (K050558)	52
6061	Aug. 22, 2005 Internal FDA memo reviewing BPV's Responses to FDA AI re G2 (K050558)	54
5343	Aug. 29, 2005 FDA Clearance Letter re G2 Permanent (K050558) (Substantial Equivalence)	56
5324	July 8, 2005 BPV's original IDE submission re G2 EVEREST Study (G050134)	58
5322	Nov. 2, 2005 FDA Grants Full Approval of G2 EVEREST Study (G051304)	59
5340	Oct. 31, 2007 BPV's G2 Filter Retrievable Traditional 510(k) (K073090)	61
5339	Jan. 15, 2008 FDA Clearance Letter G2 Filter Retrievable (K073090) (Substantial Equivalence)	64

(Index of Exhibits Continued)

EXHIBITS

NUMBER	DESCRIPTION	PAGE
5354	Sept. 19, 2005 BPV's G2 Filter - Jugular Subclavian Delivery Kit Special 510(k) (K052578)	65
5361	Sept. 25, 2006 BPV's G2 Filter - Femoral Delivery Kit Special 510(k) (K062887)	66
5362	Oct. 26, 2006 FDA Clearance Letter G2 Filter - Femoral Delivery Kit (K062887)	68
5353	Nov. 25, 2005 FDA Clearance Letter G2 Filter - Jugular (K052578) (Substantial Equivalence)	68
5373	Mar. 7, 2008 BPV's G2 Express Filter Special 510(k) (K080668)	69
5368	July 30, 2008 FDA Clearance Letter G2 Express Filter (K080668) (Substantial Equivalence)	70
5379	Aug. 12, 2008 BPV's G2X Filter Special 510(k) (K082305)	71
5376	Oct. 31, 2008 FDA Clearance Letter G2X Filter (K082305) Substantial Equivalence	71
5272	Nov. 23, 2009 BPV's Eclipse Filter System Special 510(k) (K093659)	74
5588	Dec. 15, 2009 Letter FDA to BPV re FDA AI Demand re Eclipse (K093659)	77

(Index of Exhibits Continued)

EXHIBITS

NUMBER	DESCRIPTION	PAGE
5486	Dec. 17, 2009 Letter from BPV to FDA re Eclipse Filter System Response to FDA Questions (K093659)	80
5273	Jan. 14, 2010 FDA Clearance Letter Eclipse Filter (K093659) (Substantial Equivalence)	82
5586	May 20, 2010 BPV's Eclipse Filter Special 510(k) (K101431)	84
5589	June 22, 2010 -- FDA Clearance Letter for Eclipse Filter (K101431) (Substantial Equivalence)	84
7795	Screenshot from FDA, MAUDE - Manufacturer and User Facility Device Experience, available online at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm	87
7787	Cordis Optease Femoral Jugular Antecubital - 2013	90
7771	Braun Vena Tech LP Femoral - October 2010	91

08:30:08 **P R O C E E D I N G S**

(Proceedings resumed in open court outside the presence of the jury.)

08:30:22 THE COURT: Please be seated.

All right. Good morning, everybody.

EVERYBODY: Good morning, Your Honor.

THE COURT: I'd like to hear the argument today the defendant made -- for the motion defendants made at sidebar. 08:31:16 But before doing that, let's see if there are any matters we need to address before we start trial.

Let's start on the defense side.

You have none?

MR. NORTH: We have nothing, Your Honor.

08:31:30 MR. O'CONNOR: We have nothing, Your Honor.

THE COURT: You want to make the motion argument --

MR. NORTH: Yes, Your Honor.

THE COURT: -- Mr. North?

MR. NORTH: Your Honor, at this time, pursuant to 08:31:48 Federal Rule of Civil Procedure 50, we would like to move for a judgment as a matter of law on all of the plaintiff's claims.

First, if I could start with the issue of design defect. It's my understanding now, according to the pretrial 08:32:04 order, the only claims in the case are design and warning

08:32:07 defect claims, as well as the associated punitive damage claim.

With regard to design defect, the plaintiff's only proof in this case of a design defect is the testimony of 08:32:19 Dr. McMeeking and the testimony of Drs. Hurst and Muehrcke.

Drs. Hurst and Muehrcke broadly condemn Bard filters, but they base that upon what they say are excessive complications with regard to those filters but they have no opinions and were not allowed to even give opinions as to 08:32:41 rates of complications. So they have presented no evidence that the rate of complication with regard to Bard's filters are greater than those of competitive filters. And, in fact, in the *Daubert* orders prior to the beginning of these trials, this Court precluded both of them from offering any rate 08:33:00 opinions because they had not in a reliable fashion reviewed the literature.

If you disregard their opinions on design defect, that leaves you with the opinions of Dr. McMeeking. It's very clear under Georgia law that to prove a design defect in a 08:33:18 case of this sort involving a sophisticated product, you need expert witness. Dr. McMeeking's evidence, however, is inadequate, we believe, as a matter of law.

He admitted that he had tested only the Recovery filter and the G2. He had never tested the Eclipse. He tried 08:33:38 to extrapolate his testing of the G2 to the Eclipse on the

basis that the configuration of the two were similar. But yet he testified that the Eclipse had been electropolished and that the electropolish probably did make some difference in the fracture resistance of the device, which is what we have that occurred here.

He could not quantify that or he did not measure the effect, but he admitted that the electropolishing likely improved the fracture resistance. Yet he's never done any testing at all concerning the Eclipse filter.

And we believe that as a matter of law under Rule 50 and under the applicable risk/benefit test of Georgia law, that that is insufficient evidence to prove the design defect claim.

With regard to the warning claim, Your Honor, we will concede that there is sufficient evidence to go to the jury as to whether the warning was adequate. What we do not believe there's sufficient evidence as to is whether any alleged inadequacy of the warning was a proximate cause of Ms. Jones' alleged injuries.

It is plaintiff's burden under Georgia law to show that not only that the warning was inadequate, but also that there was a causal link between the inadequate warning, allegedly, and the injury. There is simply no evidence here.

Dr. Avino testified that he could not recall ever reading the instructions for use. He did not give any

testimony as to any concrete discussions with the sales representative that assisted him or sold products to him. In fact, the plaintiffs, although having deposed that sales representative, chose not even to submit her testimony and any evidence of her interactions with Dr. Avino as a part of their case.

Dr. Avino did testify that he would want to know certain information offered by the plaintiff in their aggressive questioning of him. However, there was absolutely no testimony from Dr. Avino that anything raised by the plaintiffs in their citation of a litany of internal documents would have changed his position regarding implanting this device. He testified to the contrary that he has, throughout his career, continued to utilize Bard filters, even after the fracture -- knowing of the fracture that happened here.

In other words, we don't believe that the plaintiffs have been able to show that any different warning would have made a difference in Dr. Avino's prescribing and implanting decisions and, as a consequence, they have failed as a matter of law to show any damage. I mean, to show a causal link.

Third, Your Honor, we would like to move as a matter of law on the plaintiff's claim for future damages in this case. The component of their claim for future pain and suffering.

There's no allegation of physical pain, future

physical pain. In fact, the plaintiff's attorneys appeared to have conceded that it's only mental worry that she's seeking as far as future damages. And, therefore, this mental worry is premised on the fear of future consequences because of this strut.

Now, the unrefuted testimony by admission of Dr. Darren Hurst, the plaintiff's expert in this case, is that the risk of any of those complications occurring with regard to that retained strut are roughly 1 percent.

We submit, Your Honor, that that does not qualify or pass muster as a matter of law to present that claim to the jury.

They have the burden of showing that it is more probable than not that future injuries will occur. They simply cannot do so when their own expert says the risk of a future injury is 1 percent.

And worry about future consequences should not be compensable, and is not under Georgia law unless that worry is reasonable. And in a situation where the risk is 1 percent, it is not reasonable and they cannot show more probable than not that any such future consequence could occur.

We would also draw the Court's attention to a case, a couple of cases, by the Georgia -- one by the Georgia Court of Appeals, one from the Northern District of Georgia.

Boyd versus Orkin, at 381 Southeast 2d 295. That's a

08:38:42 situation where the court held there must be proof that a condition or an exposure will actually cause future disease, pain, or impairment of some kind.

And, here, they simply cannot do that by a 08:39:00 preponderance of the evidence.

Also in the case of *Parker versus Brush Wellman*, at 377 F. Supp. 2d 1290, Federal District Court Judge Rick Story held that subclinical effects of an exposure in that case are not a cognizable injury under Georgia law until an actual 08:39:27 complication manifests itself.

And while not directly identical to what has occurred here or what the proof is here, we believe it is applicable. And, therefore, we do not believe the plaintiffs have met their burden as a matter of law to show that it's more 08:39:43 probable than not that they will -- that Ms. Jones will have future consequences from this retained strut and, therefore, that her fear of future consequences is reasonable and compensable.

Lastly, Your Honor, we would move for -- under 08:39:59 Rule 50 for judgment as a matter of law on the punitive damages claim.

We continue to believe that the clear and convincing evidence standard set forth in Georgia law is a significant hurdle, particularly in this case, based on this evidence. It 08:40:19 was adopted in the 1990s by the Georgia general assembly as a

matter of tort reform to make punitive damages more difficult to obtain and to limit them to cases where there is absolutely emphatically evidence, clear and convincing evidence, of that level of egregiousness necessary to support a punitive award.

Here, the plaintiff's evidence, we submit, does not rise to that level.

And the plaintiff's evidence on this record is fundamentally different from the evidence they presented to the Court at the summary judgment stage. They premised then their entire argument for punitive damages on the premise that the rate of complications with Bard filters exceed those of competitive filters. There is no evidence on this record here. They utilized at the summary judgment stage, particularly Dr. Betensky, the statistician from Harvard, who has made no appearance in this case, nor the last one.

Instead, to try to implicate Bard filters and suggest they're worse than others, they rely principally on, again, Drs. Hurst, Muehrcke, and McMeeking. But Dr. McMeeking has admitted candidly that he has no opinions in this case as to rates. He offers no opinions that Bard's filters have higher complication rates than competitive filters.

This Court, in the *Daubert* orders before trial, specifically barred Drs. Hurst and Muehrcke from testifying that Bard's filters have complication rates greater than competitors'.

08:42:04 So what we're left with is evidence that Bard's filters do have complications in some instances. Based upon a -- against a background with a concession by all the experts that all filters have complications. There's simply no
08:42:22 evidence on this record at all that Bard's filters have an excessive complication rate or complication rates greater than those recognized by all the experts.

We submit that because that premise of the plaintiff's case is not present, they simply have not shown,
08:42:41 and certainly not by clear and convincing evidence, any egregious behavior or conduct that would justify an award of punitive damages in this case.

And so for those reasons on those four points, we would ask the Court for judgment as a matter of law.

08:42:59 THE COURT: All right. Thank you.

MR. MANKOFF: Good morning, Your Honor. Josh Mankoff for the plaintiff.

I'll try to address the arguments made by Mr. North in the order he gave them.

08:43:21 Regarding design defect, we do have Drs. McMeeking and Hurst discussing the conical design which was relatively unique to the Eclipse and the retrievable line of Bard filters in comparison to the SNF filter. And, of course, they both had the permanent indication and the filter was intended for
08:43:43 permanent placement in Ms. Jones.

08:43:46 They discussed the fact that the design allowed for this unique injury with the caudal migration leading to the cascade of failures, the tilt, the perforation, and the fracture, and then the fact that these fractured components 08:44:04 could migrate through the body and cause severe injury.

And that was an aspect of the design. And it led to this more severe type of injury.

Regarding the warnings -- and, of course, the standard here is the same as the motion -- standard under our 08:44:28 motion for summary judgment, and Mr. North and Bard made the same argument on the summary judgment motion. And regarding the warnings, the same evidence was submitted in response to that motion as has been -- has come in at trial.

The causal link has been made because the warning 08:44:52 evidence -- well, the jury could reasonably infer that had Bard given the warnings and transmitted the information that we heard they had and that Dr. Hurst testified a reasonable doctor would expect to give, that that would have made its way to Dr. Avino. He did read the IFU from time to time, and if 08:45:19 there was new significant information he would have learned of it through his peers and other ways that warnings come out.

If the sales representatives had been told of this information, and we heard that they were not, they had a duty to provide that information to Dr. Avino.

08:45:34 So the jury could reasonably infer that he would have

received those warnings.

Further, they can infer that he would have discussed that information with the Joneses and so that risk to benefit decision that occurs in consult with the patient would have been different. That's a reasonable inference.

Regarding future pain, Mr. North misrepresents somewhat the evidence on that aspect. We did hear that the risk for any individual injury occurring may have been 1 percent, but I believe that was 1 percent per year. In any event, the different occurrences that may happen with the embolized fragment would be additive. So there may be approximately -- and this was an estimate -- approximately 1 percent risk per year of infection occurring, but there's also 1 percent risk that it would cause occlusion or that it would move further, or that it would perforate the arteries in the lung or puncture the lung. We heard about a whole risk of potential injuries, so those are cumulative.

There's also a dispute in the evidence about whether the filter -- whether that fragment should be removed and, of course, if she does undergo surgery, that would involve additional pain.

The case Mr. North cited, *Boyd*, has language about -- in that case, the injury was whether the -- whether there was any evidence that there was an injury in the case. It involved, I believe, elevation of a certain blood level or

08:47:30 test or something like that. And the language in that full quote talks about any indication of future injury, and there was none, apparently, in that case.

Regarding punitive damages, there's clearly evidence 08:47:44 that these filters are all linked. Obviously they're predicates of each other. But we heard regarding the design of the filter, they all had the conical design.

Starting with the Recovery, Bard became aware of significant risks. They didn't -- they had a pilot study. 08:48:08 They knew that they should do a long-term clinical study. They never did that. Instead they redesigned and came up with the G2 filter. They didn't fully test that and they learned and they knew about this new risk. They determined it was unacceptable, and they continued to market it.

08:48:28 We heard that going from the G2 to the Eclipse they made one change. They didn't intend to address any failure that's relevant in this case. And while there's some evidence that it may have impacted fracture resistance to a small degree, we heard, it didn't address at all the cascade of 08:48:55 events.

So there's still this unacceptable risk of caudal migration causing the tilt and the perforation. And a marginal improvement in fracture resistance without additional testing on that point links these filters together.

08:49:19 So the knowledge they had with the G2 carries forward

to the Eclipse filter. And they had -- the only doctor involved in these filters suggested that people should use the SNF instead of the G2 when they thought that a permanent filter was warranted.

He suggested monitoring, just like Dr. Asch, who is one of the only other doctors we've heard from involving these filters, and Bard never warned doctors to conduct that monitoring. Instead we heard that they downplayed the risks. They knew they had a lack of thorough understanding of the caval anatomy. And that the filters were not being designed or tested in that environment in which the IVC could expand or collapse or twist and cause failures.

We heard that they specifically did not give sales representatives this information, so they could not pass it on to the doctors.

We heard that starting with the Recovery, when doctors learned of even a migration or a fracture occurred in their hospital, they stopped using Bard filters. So when they -- this information Bard knew was clearly relevant and putting patients at severe risk of harm.

We heard that they -- we saw that when they did the migration testing on the G2 filter that they moved the goal posts. They consciously adjusted the standards regarding the acceptance criteria and even the temperature at which they ran these tests in order to meet their own internal standards to

put these filters on the markets.

At the same time they had new design, two new designs, in the works that were going to specifically address the issue introduced with the G2 filter that carried through to the Eclipse: The caudal anchors on the Meridian filter, and then a whole host of changes on the Denali.

So they had direct -- it's clear and convincing evidence of the direct knowledge they had of the issues with this filter that they were not warning about and not addressing.

There's no evidence that Bard delivered any of these warnings in any form to Dr. Avino. And he testified he was not aware of any of this internal information.

If the Court has no questions, then that concludes --

THE COURT: Okay. Thank you.

Mr. North, did you want to say anything else?

MR. NORTH: Your Honor, the only thing I would respond to specifically is on the punitive damages. Even if you accept all of what I would characterize as their Monday morning quarterbacking of Bard's development efforts over the years, even if you accept all of that evidence as true it still does not rise, in our view, to the level necessary to justify punitive damages because a fundamental premise in their argument is missing, and that is there is no evidence that Bard's filters have these complications more so than

08:53:26 competitive filters.

And all of their experts admit that there's no such thing as a perfect filter, all these filters out there in the market have these complications. The FDA knows it, the SIR 08:53:37 knows it, everyone knows it.

So all they're saying, their evidence is suggesting is we could have done even better, but they have not established that our rate was unacceptable in the first instance or greater than competitors'. And we believe that 08:53:54 does not rise to the level of the clear and convincing evidence necessary.

MR. MANKOFF: If I may respond on that point, Your Honor?

THE COURT: Yes. Go ahead.

08:54:08 MR. MANKOFF: That evidence comes on -- in on two points. One is we heard evidence that the SNF was considered very safe and had virtually no failures, and, further, the evidence is that the risk involves both the rate -- or the probability of the harm occurring, as well as the severity. 08:54:33 And in this case we heard that the severity of the fracture was greater.

THE COURT: So are you agreeing that in this case there's no evidence that the rate of complications for the G2 line exceeded the complications in competitor devices?

08:54:48 MR. MANKOFF: No, I disagree with that proposition.

There's -- the rates were higher. We heard the rates were higher for the SNF filter, and there was also evidence that when they did comparisons with other filters they found a statistically significant difference with several filters.

THE COURT: Of the Recovery; right?

MR. MANKOFF: I believe it involved the Recovery and the G2 filter.

THE COURT: Can you remember the specific evidence on comparing G2 to other competitor devices?

MR. MANKOFF: Yeah, I believe it came in through a health hazard evaluation.

And the Wong deposition.

THE COURT: Okay. Give me just a minute, please.

All right. With respect to the first argument I'm not persuaded that I should grant judgment on the design defect claim. I do believe that Dr. McMeeking described the design defect in the G2 line of filters that's been described here, the conical design, the propensity to caudally migrate, and the fractures that result. And there's been a number of different points of evidence that the Eclipse is essentially the same design as the G2.

The fact that Dr. McMeeking did not personally test an Eclipse filter, in my view, does not undercut all of the other evidence, and I think it's a jury question as to whether or not his testimony and that of the other doctors establishes

08:57:24 a design defect.

I'm also going to deny the motion with respect to the failure to warn claim. It's a causation argument that's been made.

08:57:34 Dr. Avino testified that he expects manufacturers will inform doctors of anything in their product that is not safe, that he talked with the Bard sales representative, Melanie Velice, about the IVC filters. He discussed complications with her, and he also learned more about IVC

08:57:56 filters from meetings with colleagues, and he did sometimes read the IFU.

There has been evidence that sales representatives were not told of complication rates and that sales representatives, if told of such rates, would be obligated to

08:58:11 share them with doctors.

Dr. Avino said he would want to know if rates of complications were higher than competitive filters. He would want to know if rates of migration, performance, and fracture were four times higher than of all other filters, referring to

08:58:33 the 2004 HHE. That fracture rates would be important to him, and similar testimony.

Whether or not that is sufficient to establish causation I believe is a jury question.

As far as the risk of future damages, I think that

08:58:49 also is -- or I should -- the proof of further damages, I

08:58:53 think that also is a jury question. It's true that on cross-examination Dr. Hurst said 1 percent per year.

Dr. Muehrcke said it was a risk that placed the plaintiff a breath away from death, and with -- if the jury 08:59:09 believes that, it seems to me, the jury could conclude that the plaintiff has a reasonable basis for worry if that's the category of punitive -- or, pardon me, of compensatory damages to be sought. And I think that is, again, a jury question.

I think all the arguments made by the defendants on 08:59:28 this motion are good jury arguments. But, in my view, they do not support a judgment in favor of defendants at this point.

And on punitive damages, I think the evidence is essentially the same as in the Booker case. That is, there is evidence that the defendants were aware of complications that 08:59:48 were not known to the public, that were unacceptable, that resulted in adjustments of criteria within the company, none of which was shared with the public.

It seems to me that it is possible a jury could find that that evidence shows a callousness that satisfies the 09:00:08 Georgia standard for punitive damages, so I'm going to deny the defendants' motion.

All right. We'll bring the jury in.

(The Court and the courtroom deputy confer.)

THE COURT: Counsel, we apparently are missing a 09:00:52 juror. So --

09:00:53 No word from the juror?

THE COURTROOM DEPUTY: They called and said they're going to be late. We didn't know how long.

That was like 20 till 8:00.

09:01:05 THE COURT: All right. Apparently the juror called and said he or she will be late. We'll wait a few minutes and see if the juror arrives.

MR. O'CONNOR: Your Honor, can we assume there's at least five minutes?

09:01:18 Oh. I'm sorry, I thought we were going to take a recess. I apologize.

THE COURT: You mean you want to step out of the courtroom for a few minutes?

MR. O'CONNOR: Please.

09:01:28 THE COURT: You can. That's fine.

(The jury entered the courtroom at 9:09.)

THE COURTROOM DEPUTY: Come to order.

THE COURT: Thank you. Please be seated.

Good morning, ladies and gentlemen.

09:09:50 JURORS: Good morning.

THE COURT: We will pick up where we left off yesterday afternoon.

So you may proceed, Mr. North.

MR. NORTH: Thank you, Your Honor. And before I

09:09:57 begin, I have copies for the Court of the previous

transcripts in case they become necessary.

THE COURT: Okay.

DR. DONNA-BEA TILLMAN,

recalled as a witness herein, after having been previously duly sworn or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N (CONTINUED)

BY MR. NORTH:

Q Good morning, Dr. Tillman.

A Good morning.

MR. NORTH: If we could bring up Exhibit 5126.

BY MR. NORTH:

Q I believe we were looking at this exhibit yesterday when we concluded for the afternoon?

A Yes, we were.

MR. NORTH: And I believe this has been admitted. If we could display it for the jury.

THE COURT: Yes.

BY MR. NORTH:

Q And remind us again what the purpose of this document was.

A So this is the special control guidance document that FDA wrote to describe the special controls or the things that have to be done in order to support a premarket submission for an IVC filter.

Q And when was this published?

A So it was published in November of 1999.

09:11:00 Q And was this developed as a -- by the FDA as a part of the down-classification process for IVC filters?
A Yes, it was.
MR. NORTH: If we could turn to page 3.
09:11:20 BY MR. NORTH:
Q In looking at the first paragraph beginning with -- well, beginning with the first paragraph, what does this guidance document say is the purpose or the importance of the guidance document to manufacturers of filters?
09:11:37 A So this is the guidance document that explains what are the things that a medical device manufacturer who is making a filter needs to do in order to mitigate the risks of filters. And so this guidance describes the testing and the evidence that needs to be provided in order to demonstrate that one of
09:11:58 these devices is substantially equivalent to a predicate device.
MR. NORTH: If we could go to page 4.
BY MR. NORTH:
Q At the top of the page, does the FDA say anything about
09:12:14 the need for filters with certain classification of patients?
A So in this guidance, FDA describes sort of the public health problem of recurrent pulmonary embolism and talks about the rates at which they occur, and it talks about what the purpose of IVC filters are.
09:12:42 MR. NORTH: Now, if we could turn to page 5.

09:12:49 BY MR. NORTH:
Q Does the FDA here begin to set forth various tests that they -- that the agency recommends for a filter manufacturer?
A Yes, they do. As we mentioned the other day, there's sort
09:13:01 of a standard set and types of tests that are done with medical devices. And so FDA sort of is going through in this guidance listing the major types of tests, and then details around the device-specific testing that needs to be done for IVC filters.
09:13:16 MR. NORTH: If we could look at the second sentence under subsection B, "It is the submitter's responsibility."
BY MR. NORTH:
Q Does the agency place the obligation to perform these tests on the manufacturer?
09:13:33 A Yes, most definitely.
MR. NORTH: If we could turn to the next page, please.
BY MR. NORTH:
Q Does the FDA -- what sort of specific test does the FDA
09:13:46 prescribe or suggest as a part of this guidance document?
A So this is a set of what I would call bench testing that's specific to IVC filters, and so FDA has considered the potential risks of IVC filters. And then for each of those different risks, they've identified a set of tests that are
09:14:06 done in order to demonstrate that those risks have been

09:14:08 mitigated.

So some of these tests -- for example, there's one about simulated deployment so can the delivery system for the filter be introduced into the patient and the filter be 09:14:21 correctly deployed? And then they go through a bunch of other kinds of tests.

Q Let's look at number 4.

Does the FDA specifically prescribe or suggest testing for the risk of filter fracture?

09:14:35 A Yes. Filter fracture is a known risk of IVC filters. And in this section FDA describes that companies need to conduct bench testing that reflects worst case respiratory and diaphragmatic movements in order to demonstrate the filter can withstand the mechanical forces it will be subjected to. And 09:14:58 they also say that the filter needs to be tested to make sure that it can resist corrosion.

Q Let's look at Number 5.

Does the FDA also suggest specific types of tests to evaluate the risk of caval penetration or filter migration?

09:15:16 A Yes, it does. The guidance basically says that companies have to develop test methods to ensure that the filter will stay in place under the expected conditions of use and that it will not have a tendency to perforate the caval wall.

MR. NORTH: If you could turn to the next page.

09:15:38 BY MR. NORTH:
Q Does the FDA also offer some guidance with regard to clinical studies pertaining to IVC filters?
A Yes. So the guidance basically says that if you're
09:15:51 manufacturing a new filter, so if it's a company's first ever filter, that those devices will generally require clinical data. And also that if a company makes significant modifications to a device, that those modified devices may also require clinical data.
09:16:09 Q Let's look at the paragraph on that page that begins for the indications outlined previously.
In that first sentence, what does the FDA specifically say about the risks and benefits of IVC filters?
A So FDA says that for the particular set of indications
09:16:28 that the guidance talks about, and that is the set of indications for which FDA has down-classified IVC filters, that the risks and benefits are well documented. That basically the FDA and the -- FDA understands what the risks are and the benefits.
09:16:47 Q A couple of lines down, beginning with the sentence "Although," does the agency say anything about how these risks are reflected in the medical literature?
A Yes. So FDA says that the risks are well described in the literature.
09:17:14 Q Beginning at the bottom of that page, does the FDA discuss

09:17:18 specific risks that it has seen in the literature and weighed?
A Yes. So in this section FDA is describing the known risks of IVC filters and then discussing how they should be evaluated in the clinical trial.
09:17:35 MR. NORTH: If we could turn to page 9, please.
BY MR. NORTH:
Q Does the FDA recognize that death can be a potential complication with respect to IVC filters?
A Yes. Absolutely. There's a section in here called Death
09:17:55 where FDA discusses that there have been deaths reported with IVC filters and that if deaths occurred during the clinical study that they need to be documented and provided for FDA's review.
Q Look at the next section. Does the FDA recognize
09:18:14 migration is a known risk of IVC filters?
A Yes. In fact the first paragraph here says that minor filter migration in the caudal or cephalic direction is commonly reported and does not appear to be associated with clinally significant events.
09:18:32 And then the FDA also goes on in this paragraph to talk about what they call true migration, which is migration that is more significant. So they also recognize that that is a potential -- potential adverse event associated with filters.
09:18:48 MR. NORTH: If we could go to the next page, please.

09:18:57 BY MR. NORTH:
Q Number 5, does the FDA recognize that caval penetration or perforation is a known risk of these devices?
A Yes, they do.
09:19:07 Q Number 6, does the FDA recognize that tilting is a known complication?
A Yes. The guidance clearly lists filter tilting and angulation as a potential complication.
Q In number 8, does the agency recognize that filter
09:19:29 embolization is a known risk?
A Yes, they do.
Q And what is filter embolization?
A So filter embolization usually refers -- usually filter migration is movement of the entire filter. Filter
09:19:47 embolization often reflects movement of or -- or fracture of the filter and embolization of a part of the filter.
Q Does the guide also acknowledge that the FDA recognizes fracture as a risk of filters?
A So I think that clearly filter embolization is a byproduct
09:20:17 of filter fracture, so I would say that FDA does. And they talk about the fact that filter embolization can be -- is a serious complication, but it may have different kinds of clinical effects, some of them are asymptomatic and some patients who have those may have very catastrophic outcomes.
09:20:49 MR. NORTH: Let's look, if we could, back at page 8,

09:20:51 the second section, "These complications can result in."
BY MR. NORTH:
Q And does the FDA here recognize fracture as a potential risk?
09:21:01 A Yes. It is explicitly listed here.
MR. NORTH: Now, if we could turn to page 11.
BY MR. NORTH:
Q Does the FDA in the guidance document suggest certain parameters for the labeling or instructions for use to
09:21:24 accompany these devices?
A Yes. This -- basically FDA reviewed the labeling for devices that were currently being marketed prior to writing this guidance document, and then they believe -- they've recommended here changes that should be made to the labeling
09:21:41 in order to make sure that the labeling is consistent among different medical device manufacturers.
Q And if we could look at the last sentence on that page, the attachment.
Does the FDA go so far as to provide a format for the
09:21:56 labeling for IVC filters?
A Yes, they do. It's provided as an attachment to this guidance document.
MR. NORTH: If we could look at the next page, page 12.

09:22:12 BY MR. NORTH:

Q Is this the attachment where the FDA in the guidance document prescribes a certain format and structure for the instructions for use for IVC filters?

09:22:21 A Yes, it is.

Q In your opinion, do these various aspects of the guidance document that the FDA came up with, did it reflect the agency's considerations in down-classifying filters?

A Yes, it did. This guidance document basically was the

09:22:48 documentation of FDA's determination that it understood the potential risks and that it understood what needed to be done to mitigate those risks. And then by presenting the testing and the labeling information that's recommended in this guidance document, FDA believes that if a company follows

09:23:06 this, then the device should be such that the benefits of the device would outweigh the risks.

Q Dr. Tillman, at the request of my law firm, did you review documents regarding the regulatory history of Bard's IVC filters?

09:23:21 A Yes, I did.

Q And did that include the regulatory history of the Recovery filter, the G2 filter, and the other variations of the G2 filter, and the Eclipse filter?

A Yes, I did.

09:23:34 Q Were there certain types of documents or information you

09:23:38 wanted to review for your analysis in this case?
A Yes. So when I started in this case, the first thing I wanted to receive was copies of all of the 510(k) submissions. I also looked at copies of the communications between Bard and
09:23:53 FDA during the 510(k) process.

Then, when I learned more about what was going on in the postmarket setting, I asked for documents relating to Bard's internal communications. So when they were looking at how the product was performing, once it was released into the
09:24:09 market, they were getting information back about complaints and adverse events, so I asked for information documenting what they did to address that. I received and reviewed documentation about the testing that Bard did in response to those events.

09:24:24 Then, when Bard -- in response to those postmarket events, Bard interacted with FDA and there were meetings between FDA and Bard about how they talked about those events. So I reviewed all of that documentation.

I reviewed expert reports from the plaintiffs. I've
09:24:43 reviewed some depositions of Bard employees that are relevant to the FDA process. And then I reviewed relevant FDA guidance documents like some of the ones we've talked about today.

Now, I don't know if that is an exhaustive list but it's much of what I looked at.

09:25:00 Q During your work in this case, if you wanted to review

09:25:02 additional documents, did you have the opportunity to do so?
A Absolutely. If I felt like I needed an additional document, if I saw a reference to a test report, I contacted the attorneys that I work with and asked for the document and
09:25:16 it was provided to me.
Q What type of regulatory submissions did Bard submit for the Recovery filter and G2 filters?
A So Bard submitted 510(k) premarket notifications.
Q And what was the predicate device for the Recovery filter?
09:25:34 A So the predicate for the Recovery was the Simon Nitinol filter.
Q And what was the predicate for the G2 filter?
A And the predicate for the G2 was the Recovery filter.
Q At the time that Bard submitted the 510(k) application for
09:25:49 the G2, was the Recovery filter legally on the market?
A Yes, it was.
Q To what extent, if at all, was Bard required under the regulations or the FDA's procedures to compare the G2 to any other IVC filter besides the Recovery filter?
09:26:12 A So a company is allowed to select its own predicate device, so there's no requirement that it compare to any particular device. Given the fact that the whole intent of the G2 program was to develop a device that was the next generation after the Recovery, it makes sense to me that the
09:26:30 Recovery would be the appropriate predicate. If Bard had come

09:26:33 to me as a regulatory consultant and asked me to prepare that 510(k), I would have said, well, we should use the Recovery as a predicate device.

Q What was the purpose -- what's your understanding of the 09:26:44 purpose for changing the Recovery filter to the G2 filter?

A So when the Recovery filter was cleared and was marketed, Bard observed that there were some adverse events occurring relating to filter fracture and migration. These were known adverse -- known types of adverse events, but Bard determined 09:27:04 that it could improve the performance of the device and make some changes to it to improve its fracture resistance and its ability to resist migration. So the G2 represents sort of the next generation improved product.

Q Now, over time had the -- did you see evidence that Bard 09:27:21 and the FDA had been in communication about the performance of the Recovery filter after the time it was initially cleared by the agency?

A Yes. Absolutely. Bard was definitely in communication with FDA. I have seen minutes of phone calls where Bard 09:27:39 employees reached out to FDA to inform them about what they were observing with the Recovery filter and the efforts that they were taking to communicate this information with health care providers.

Q Did you prepare a chronology of the various communications 09:28:07 that Bard had with the FDA regarding the Recovery filter?

09:28:10 A Yes, I did. There were a number of interactions, and so to try to help kind of keep them straight in my own mind I created a chronology that sort of laid out the different communications and the dates on which they occurred.

09:28:25 MR. NORTH: Could we bring up Exhibit 7928.

BY MR. NORTH:

Q Is this the chronology you prepared?

A Yes, it is.

MR. NORTH: Your Honor, if we could have permission

09:28:37 to display this to the jury.

MR. LOPEZ: I don't think this is in the report, Your Honor.

THE COURT: Is this in the report?

MR. NORTH: Not as a demonstrative. The subject

09:28:48 matter of all of this is.

THE COURTROOM DEPUTY: I've reported it. It's an alarm in the tech room.

THE COURT: Do you know what the beeping is?

THE COURTROOM DEPUTY: Yes. It's a panel in the

09:29:09 tech room. And they're going to fix it at break.

THE COURT: Hold on just a minute, Counsel.

If this is not in the report, I'm going to sustain the objection under Rule 26(a)(2)(B)(iii), which requires exhibits used to summarize opinions.

09:29:31 MR. NORTH: Thank you, Your Honor.

09:29:31 BY MR. NORTH:

Q Can you tell us what sorts of communications the FDA had with Bard regarding the performance of the Recovery filter?

A Yes. So Bard initially approached FDA to talk to them about a letter that they planned to send to physicians informing them about some of what they were seeing with the Recovery filter. FDA provided some feedback to Bard on the contents of that letter.

Bard and FDA also had some conversations around Bard's plans to engage with the physician community and to try to get additional feedback about certain events that were occurring and to hear from the physician community about that as well.

Q During the course of the marketing and sale of the Recovery filter, did Bard produce a Dear Colleague letter sent out to the medical community about complications?

A Yes, they did.

Q And did Bard consult with the FDA regarding the contents of that letter?

A Yes. They submitted a draft of that letter to FDA and asked FDA to review it and provide feedback on it. And FDA actually provided some suggestions, and Bard made those changes and then sent the letter out.

Q Did Bard likewise send a second letter, a Dear Doctor letter about complications with the Recovery filter out to

09:30:55 physicians who had utilized the device?
A Yes, they did.
Q And did Bard again consult with the FDA regarding that second letter?
09:31:04 A Yes, they did.
Q What sorts of evidence did you see regarding the agency's review of those letters and discussions with Bard?
A So I reviewed --
MR. LOPEZ: Excuse me. That calls for a lot of
09:31:31 hearsay, Your Honor. Going back and forth, her talking about the conversations going back and forth.
THE COURT: I think he just asked what documents she saw. That answer won't be hearsay.
So, but we should just describe documents before
09:31:45 talking about contents.
MR. NORTH: Yes.
THE WITNESS: So I reviewed minutes of meetings that -- of phone calls that Bard had with the agency, and I also reviewed some drafts of the letters that Bard proposed
09:31:58 to send.
MR. NORTH: If we could bring up Exhibit 6075.
BY MR. NORTH:
Q Have you seen this particular document?
A Yes, I have.
09:32:21 Q And what is this document?

09:32:23 A So this is minutes of a phone call between Bard and FDA to talk about a conversation between an FDA reviewer and a Bard representative regarding the -- Bard's -- what Bard was seeing with the Recovery filter and Bard's plans to provide a Dear
09:32:42 Doctor letter to health care providers.

Q Who was the author of these particular minutes?

A So the minutes were written by FDA, by Lisa Kennell, who is a reviewer --

MR. LOPEZ: I'm going to object. I'm looking on the
09:32:58 reliance under the FDA production number that appears on here. It's not on the list, and I don't think it's discussed in the report.

THE COURT: Could you point out the location on the reliance list, please.

09:33:08 MR. NORTH: Your Honor, on the reliance list it is on page 12. In the report it's on page 51.

MR. LOPEZ: Page 12. I'm looking at the FDA production number.

THE COURT: Can you tell me where on page 12.

09:33:28 MR. NORTH: On page 51 of the report, at the paragraph beginning "In reviewing." It quotes from that memo.

THE COURT: That is Exhibit 6075?

MR. NORTH: Yes, Your Honor.

09:33:48 THE COURT: All right. Objection is overruled.

09:33:52 BY MR. NORTH:

Q Dr. Tillman --

MR. LOPEZ: Your Honor, I'm sorry, but the FDA production number that is shown is different than what's in the report.

09:33:57

THE COURT: Have you compared the language on page 51 to the document, Mr. Lopez?

MR. LOPEZ: What's the footnote number?

THE COURT: It's page 51.

09:34:05 MR. LOPEZ: I see the 51, but it refers -- six footnotes here.

THE COURT: It's not in the footnote. It's in the paragraph beginning "In reviewing."

MR. LOPEZ: Okay.

09:34:12 THE COURT: There's a quotation of four, five sentences.

MR. NORTH: Your Honor, I believe what he's referring to, in the reliance list it has the FDA production and it has a broad range, like from page 1 to page 1,000, and

09:34:25 this is within those that is there.

MR. LOPEZ: I'm sorry. The FDA production number here is different than the one that's in the report. So.

THE COURT: Well, Counsel, come to sidebar, would you.

09:34:38 You can stand up, ladies and gentlemen.

09:34:39 (Bench conference as follows:)

THE COURT: Show me what you're talking about, Mr. Lopez.

MR. LOPEZ: Well, the document's up. Says FDA

09:35:01 production 1019.

THE COURT: You said it's not in the reliance list.

MR. LOPEZ: Yeah, I didn't see it in the reliance list.

THE COURT: Where is it in the reliance list?

09:35:11 MR. NORTH: Right here, Your Honor. It starts from 1004 to 1370. Beginning and end numbers.

MR. LOPEZ: But it's not referenced. He doesn't cite to it in the report.

THE COURT: Well, but it is clearly in the reliance

09:35:23 list. Do you agree?

MR. LOPEZ: Now that I know it's on list. But --

THE COURT: Okay. But do you agree that this is a quote from it?

MR. LOPEZ: I don't know.

09:35:29 THE COURT: Well, it seems to me it's your burden to show that it is if it's quoted and they're representing to me it's in the document.

MR. LOPEZ: But, Your Honor, what I'm saying is that the report does not refer to this -- the document on the

09:35:41 screen.

09:35:42 MR. NORTH: It refers to 18 and 20. All right in there.

MR. LOPEZ: I know 19 is between 18 and 20, but --

MR. NORTH: And it's a direct quote from right

09:35:54 there.

MR. LOPEZ: Is this a typo?

MR. NORTH: Must be.

THE COURT: Well, you're avowing that this is a direct quote from the exhibit.

09:36:02 MR. NORTH: I just saw it, Your Honor.

THE COURT: Okay. On the basis of that avowal, I will overrule the objection.

(Bench conference concludes.)

THE COURT: Thank you, ladies and gentlemen.

09:36:20 MR. LOPEZ: For the record, I have 403 and 802 objections to the same document.

THE COURT: I don't think there's been a motion to admit it into evidence yet.

MR. LOPEZ: Okay.

09:36:34 BY MR. NORTH:

Q Dr. Tillman, how is it that you came to have access to this internal FDA memorandum discussing the agency's review of Dear Doctor letters that Bard was intending to send?

A So this was acquired -- yesterday we talked about the

09:36:55 Freedom of Information Act, so this was acquired through a

09:36:59 Freedom of Information Act request that was submitted to FDA about information relating to this particular 510(k). And in response to that FDA provided what is called the administrative record, which documents the actions that FDA
09:37:14 had during the review of the 510(k) and afterwards. And that's how this document was received.

MR. NORTH: Your Honor, at this time we tender Exhibit 6075.

MR. O'CONNOR: Objection, Your Honor. 403 and
09:37:27 hearsay 802.

THE COURT: Okay. What is your response on hearsay?

MR. NORTH: Your Honor, 803(8), a public record. The memorandum specifically discusses the office's activities subsection (A)(i) of 803(8).

09:37:51 MR. LOPEZ: It's hearsay within hearsay in this document, Your Honor.

THE COURT: Where is the hearsay within hearsay?

MR. LOPEZ: I need to see the next page. I think they're quoting from some other people.

09:38:00 THE COURT: Do you have a copy of this exhibit, Mr. North?

MR. NORTH: Yes, Your Honor. Just a minute.

MR. LOPEZ: Second paragraph, Your Honor, there's hearsay.

09:38:27 THE COURT: Second paragraph of what?

09:38:29 MR. LOPEZ: On the first page.
THE COURT: Okay. Hold on.
What's your response, Mr. North?
MR. NORTH: Are we talking about the second page?
09:39:13 THE COURT: Second paragraph, first page.
MR. NORTH: First page?
THE COURT: Yes. Second sentence.
MR. NORTH: First of all, Your Honor, I don't think that particular line within there is being asserted for
09:39:34 the -- I mean, being offered for the truth of the matter asserted. It is simply to document the discussions between the agency and Bard. It does not quote and it also helps to explain the conduct and the decisions of the agency.
THE COURT: Well, I don't think we can go so fine as
09:40:01 to be giving instructions on sentences within documents. So I think we should redact that sentence which is hearsay within hearsay. And with that sentence redacted, I'll admit the document 6075.
MR. NORTH: Okay. And I would note there's another
09:40:17 redaction that needs to be made in accordance with previous orders before we display --
THE COURT: The one already that's on the page, you mean?
MR. NORTH: What?
09:40:25 THE COURT: You mean the one that's already on the

document?

MR. NORTH: Yeah.

THE COURT: So it's admitted subject to redacting the second sentence in the second paragraph.

MR. LOPEZ: Excuse me, Your Honor. He's saying he wants further redactions on this. I'd like him to at sidebar tell us which ones --

THE COURT: No, we're not going to have another sidebar. This document is admitted. You can talk about redactions --

Counsel. Talk to me.

-- we can talk about redactions if there's an issue later. We're moving forward with this exhibit.

MR. NORTH: Thank you, Your Honor.

(Exhibit 6075 admitted.)

MR. NORTH: Could we display just the first paragraph to the jury?

THE COURT: If you could do that, yeah, without the --

MR. NORTH: The first paragraph.

THE COURT: Yeah, that's fine.

Yeah, that may be displayed.

MR. NORTH: Thank you, Your Honor.

BY MR. NORTH:

Q Tell us, if you will, does this explain the purpose of or

09:41:17 what the subject of these discussions were?
A Yes. So what happened was Bard decided, based on the information it had in the postmarket setting that it needed to make some changes to the labeling to add some additional
09:41:31 information, cautionary information to the labeling. And when you make changes to your labeling, sometimes you need to actually submit a new 510(k).

And, so, Bard had approached FDA, and that's what this submission was, with these changes to the labeling and
09:41:47 the Dear Doctor letter to ask FDA if we make these changes to the labeling, do we need to submit a new 510(k).

And if you don't need a new 510(k), then what you submit is what is called an amendment to the 510(k).

So if you read this sentence, what FDA is telling
09:42:07 Bard, Mary Edwards, is that an amendment to the 510(k), which basically describes the changes to the labeling, would be the appropriate route in order for Bard to make the labeling changes and to get FDA's input on the Dear Doctor letter.

MR. NORTH: Your Honor, could we display the second
09:42:28 page of this?

THE COURT: You may.

MR. NORTH: Thank you.

BY MR. NORTH:

Q Starting in the paragraph "I shared," does the --
09:42:39 Lisa Kennell from the FDA indicated what she had done as far

09:42:46 as analyzing what was going on?
A Yes. So there's a bunch of different offices at FDA. So the office I worked for and the office that Lisa Kennell worked for is the Office of Device Evaluation. And those are
09:42:59 the people responsible for doing the premarket reviews and reviewing the 510(k)s.
There's another office, the Office of Surveillance and Biometrics, which they call OSB, and there is a person there, Jenny Liu, who I knew very well when I was there, who
09:43:18 was responsible for looking at postmarket safety data.
And so what happened was, when Lisa Kennell became aware of this information as documented in this memo, she reached out to Jenny Liu and asked her if she had comments on the Dear Doctor letter language, and Jenny Liu then went and
09:43:34 searched the databases, and this would have been the MAUDE database that we talked about yesterday, which is where the adverse event data lives, and Jenny Liu said that she did a search of the MAUDE database and that she identified some questions about what they were seeing in the MAUDE database.
09:43:51 Q And if we could look at the second sentence that says "we agree that the bolded statement." Did she make any comment about the IFU as it presently read?
A Yes. So basically what they're -- what Lisa Kennell is saying in this memo is that the bolded statement that Bard is
09:44:13 proposing, which apparently is regarding weighing the risk and

benefit of using the filter, that Lisa Kennell believed that this should address the issue, but that Bard needed to continue to monitor the adverse events.

Q Does this memorandum indicate to you that the agency was looking at information that Bard had provided regarding the performance of the Recovery filter?

A Yes. I mean, this suggests that both the premarket office and the postmarket safety office were aware of the adverse event data regarding the Recovery filter.

Q Does this information indicate to you that the FDA was independently reviewing and tracking complications associated with the Recovery filter?

MR. LOPEZ: Your Honor, speculation. I think that lacks foundation.

THE COURT: Overruled.

THE WITNESS: So the fact that Jenny Liu went back and did her own analysis of the adverse event data, as we saw documented in that memo, suggests to me that FDA is not just relying on Bard to tell them about the events, but it's actually looking at the adverse event data themselves and doing their own analysis.

MR. NORTH: If we could look at Exhibit 5349, please.

BY MR. NORTH:

Q Do you recognize this document?

09:45:43 A Yes. This is a 510(k) submission for what I believe was the G2 filter. It's a little confusing because when they originally submitted it they called it the Recovery, and they eventually changed it to G2.

09:46:09 Q And when was this submitted to the FDA?

A In March of 2005.

MR. NORTH: If we could look at Exhibit 5905.

BY MR. NORTH:

Q Do you recognize this document?

09:46:24 A Yes, I do.

Q And what is this?

A So this is an agenda of a meeting that Bard held with FDA to discuss what it was observing in terms of the performance of the Recovery filter and the steps that it was taking to

09:46:40 address what it was seeing.

Q And did this particular meeting, is it your understanding that it occurred soon after the initial submission of the 510(k) for the G2 filter?

A Yes, it did.

09:46:53 Q And in your experience, is it unusual for a manufacturer such as Bard to have a sit-down meeting with the FDA concerning an application?

A Yeah. It's very unusual to have this kind of meeting. And, in particular, there were a significant number of FDA

09:47:11 people that attended this meeting, both from the premarket

09:47:14 review side, the people who review the 510(k)s, and from the postmarket safety side. So this was somewhat of an unusual meeting.

Q What did the -- following this meeting, what did Bard do 09:47:27 with regard to its regulatory track with the G2 filter?

A So originally when Bard submitted the 510(k) for the G2, they said to FDA we've got a cleared device, the Recovery filter. It's cleared for permanent indications and it's cleared for retrievability and we've made some modifications 09:47:49 to it to improve its fracture resistance and its migration resistance and we're going to submit what is called a Special 510(k).

And a Special 510(k) is a kind of 510(k) that a company can submit when they make changes to their own device 09:48:08 that don't change the indications for use and that don't change its fundamental scientific technology.

So the idea is that medical devices are constantly being modified. Engineers are constantly tweaking devices, and when they do that, companies have to submit new 510(k)s. 09:48:25 And this Special 510(k) program is sort of an abbreviated 510(k) that allows manufacturers to submit summary of data rather than the full data, if they only make a minor modification.

Q What sort of additional information did Bard submit to the 09:48:46 FDA when it submitted a regular 510(k) for the G2 filter?

09:48:51 A So when Bard originally submitted this as a special and FDA came back and said it can't be a special because we're going to need some clinical data, and at that point in time Bard sort of bifurcated the pathway.

09:49:09 Q Did Bard submit a 510(k) for initial clearance of the device as a permanent filter?

A Yes. So what happened then was FDA said to Bard you're going to need clinical data if you want to indicate this new G2 filter for retrievability. But if you want to just

09:49:29 indicate it as a permanent filter, you don't need clinical data.

So Bard then went down two paths. They submitted -- they updated this 510(k) to become a traditional 510(k), they provided all of the test reports, and then FDA will review

09:49:47 that 510(k) for permanent indications. And then, meanwhile, Bard and FDA worked on designing and developing a clinical study that would be used to support another 510(k) later on for the retrievable indications. So we sort of split the G2 into a permanent pathway and a retrievable pathway.

09:50:08 Q Did Bard submit as a part of the G2 application for permanent use of the filter a DV and V protocols?

A Yes. Bard submitted basically the testing of the new filter that was consistent with what FDA asked for in the guidance document we talked about, and that testing called

09:50:30 design verification and validation testing, or DVT.

09:50:38 Q And did Bard submit animal studies?
A Yes. Bard did submit an animal study as well.
Q And did Bard submit information concerning its rationale regarding fatigue testing?
09:50:51 A Yes. All of that information was provided in the traditional 510(k) for the permanent indication Recovery -- G2 filter.
MR. NORTH: If we could bring up Exhibit 6064, please.
09:51:07 BY MR. NORTH:
Q Have you seen this document before?
A Yes, I have.
Q And can you tell us what that is?
A So this is a review memo. So when FDA reviews a 510(k), 09:51:30 there's a lead reviewer assigned, and there might be other reviewers on the team as well. And as I mentioned before, those reviewers document their findings in a review memo.
So this basically says -- describes what the device is, what FDA looked at, what questions it asked, and then what 09:51:49 evidence was provided by the company to demonstrate substantial equivalence.
So the lead reviewer on this particular 510(k) was Angela Smith, and this documents her findings in the review.
MR. NORTH: Your Honor, at this time we would tender 09:52:07 Exhibit 6064 for admission.

09:52:10 MR. LOPEZ: No objection, Your Honor.
THE COURT: Admitted.
(Exhibit 6064 admitted.)
MR. NORTH: If we could turn to page 3, please.
09:52:46 Your Honor, could we display this in front of the jury?
THE COURT: Yes.
BY MR. NORTH:
Q Had FDA asked some questions of Bard regarding its
09:52:58 submission for the G2?
A Yes, they had. And FDA calls those questions deficiencies. So when FDA has a question for a company in a submission, they send them a deficiency letter.
Q And does this particular memo from the FDA's deliberations
09:53:16 discuss their analysis of Bard's response to those deficiencies?
A Yes. In this memo FDA documents the questions that they asked. So number 1 is the first question FDA asked, and then in bold is FDA's analysis of the response from Bard. And then
09:53:37 number 2 is the second question FDA asked, and in bold after that is FDA's assessment of the response received from Bard.
MR. NORTH: If we could look at page 5, please.
BY MR. NORTH:
Q And under number 2 there, did the agency provide some
09:54:15 comments regarding the labeling for the G2?

09:54:17 A Yes, they did. So basically FDA noted that while the indications for use for the G2 reflected the fact that it was only indicated for permanent placement, that the name might suggest that it could be removed. And so FDA requested that 09:54:37 the device name be changed from Recovery to something else.

Q Are these sorts of memos typical for the agency to prepare when reviewing devices?

A Absolutely. They're actually required. FDA has to document the basis for any decision that it makes, and every 09:54:58 510(k) submission is accompanied by an administrative record which includes all of the review memos and any telephone conversations that FDA has with the sponsor during the review.

MR. NORTH: If we could look at page 2, and just bring out the paragraph that begins "Lisa Kennell."

09:55:37 And let's -- can we delete the -- or just show that one paragraph.

BY MR. NORTH:

Q Does this indicate that the FDA had reviewed Bard's bench testing on the G2 to assess the changes that had been made to 09:55:56 the Recovery filter?

A Yes. It indicates here that FDA had reviewed the sponsor, which is Bard's bench testing, and that they -- FDA believed that that testing was adequate to support the modifications.

MR. NORTH: If we could bring up 6061, please.

09:56:24 BY MR. NORTH:

Q Dr. Tillman, can you tell us what 6061 is?

A So this is a cover sheet that basically is put on top of the administrative record when FDA gets a submission, and this

09:56:43 reflects the next round of questions. So FDA received the 510(k), they asked Bard some questions, Bard answered those questions, and that's the memo you just saw. And in reviewing that information, FDA had some additional questions. In particular about whether the animal study was relevant. And

09:57:02 so FDA went back and asked Bard some additional questions, and then this document reflects FDA's review of Bard's answer to that second round of questions.

MR. NORTH: Your Honor, at this time, subject to some redactions that will be need to be made, we would tender

09:57:22 Exhibit 6061.

MR. LOPEZ: No objection, Your Honor, but also no concessions about any redactions.

THE COURT: Well, it's admitted subject to the parties agreeing on redactions.

09:57:37 MR. NORTH: Thank you, Your Honor.

(Exhibit 6061 admitted.)

MR. NORTH: If we could turn to page 4.

Could we display, Your Honor?

THE COURT: Yes. Assuming this isn't information

09:57:54 that's going to be redacted?

09:57:56 MR. NORTH: No.

THE COURT: You may.

MR. NORTH: And if we could look at the recommendation SE with limitations.

09:58:05 BY MR. NORTH:

Q What does that mean in FDA speak?

A So what that means. So SE means substantially equivalent, so when you submit a 510(k) you -- if you're a company you want FDA to determine it's substantially equivalent.

09:58:23 Substantially equivalent with limitations is a finding FDA makes in a very small subset of 510(k)s. And what that means is that FDA has determined that there is reasonable likelihood that the device could be used off label and that such use could cause harm. So that is what SE with

09:58:44 limitations means.

And the off label use that FDA was worried about was, remember, this G2 was only being cleared for permanent indications. And even though the name was being changed from Recovery to G2, FDA wanted to make sure it was very clear that

09:59:00 the device was only being cleared for permanent indications. And so they found it SE with limitations and required Bard to put this statement that's on this slide that the safety and effectiveness of the G2 filter system for use as a retrievable or temporary filter have not been established on the labeling

09:59:22 at this time to reflect the fact that it was only being

09:59:26 cleared for permanent indications.

MR. NORTH: Could we bring up Exhibit 5343, please.

BY MR. NORTH:

Q Have you seen 5343 before Dr. Tillman?

09:59:42 A Yes, I have.

Q And what is this document?

A So this is the actual letter that FDA sends to the company. This is the SE with limitations letter, which basically gives Bard the authority to market the device.

09:59:56 MR. NORTH: Your Honor, at this time we would tender 5343.

MR. LOPEZ: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit 5343 admitted.)

10:00:03 MR. NORTH: Could we display, Your Honor?

THE COURT: You may.

BY MR. NORTH:

Q Dr. Tillman, does this letter -- is this letter consistent with the internal FDA memo we just looked at?

10:00:13 A Yes, it is. This is a standard sort of boilerplate letter that also includes the SE with limitations language that we discussed.

Q After the FDA cleared the G2 filter, did Bard conduct a clinical trial with regard to the G2?

10:00:31 A Yes, they did.

10:00:33 Q And what was -- was that clinical trial called the EVEREST study?
A Yes, it was.
Q And what was the purpose of the EVEREST study?
10:00:42 A So the purpose of the EVEREST study was to collect clinical data to support the retrievable indications for the G2 filter.
Q Now, in order to conduct a clinical trial for a use, like retrievability here, that had yet to be cleared by the FDA, 10:01:02 did the -- Bard -- was it required to file some sort of application with the agency?
A Yes. So there's a program called Investigational Devices Exemption, or IDE, and that is a program that FDA administers where if a company wants to do a clinical study of a medical 10:01:21 device that is not approved or cleared in the U.S., then they need to submit an application to FDA to ensure that the study is appropriately designed and that human subjects are appropriately protected.
MR. NORTH: If we could look at Exhibit 5324, 10:01:40 please.
BY MR. NORTH:
Q Have you seen Exhibit 5324 before?
A Yes, I have.
Q And what is that?
10:01:50 A So this is the IDE submission that Bard made to FDA

10:01:56 requesting approval to conduct the EVEREST study.

MR. NORTH: Your Honor, at this time we would tender 5324.

MR. LOPEZ: No objection, Your Honor.

10:02:04 THE COURT: Admitted.

(Exhibit 5324 admitted.)

MR. NORTH: If we could turn to page 42, please.

I'm sorry, page 57, the actual page 42.

BY MR. NORTH:

10:02:36 Q What is a study end point?

A So when you do a clinical study, clinical studies are done to answer questions. And so the purpose of this particular clinical study was to answer questions regarding the retrievability of the G2 filter and its safety and adverse

10:02:56 event profile.

So study end points are the things that the company's going to measure when they do the study in order to answer those questions.

So there were three questions basically that this

10:03:09 study was designed to look at: Procedural success, so can I get the filter in there and get it in place; clinical success, that the filter can actually be retrieved after some amount of time; and then adverse events, so what were the adverse events that were observed during the study.

10:03:31 Q What does it mean that Bard included adverse events as a

10:03:35 study end point?
A So it meant that the study was not just looking at retrievability, but it was also looking at the adverse events that would occur throughout the 30 days post filter retrieval.
10:03:49 Almost all clinical studies have both end points looking at effectiveness and end points looking at safety, like this one.
MR. NORTH: If we could bring up Exhibit 5322, please.
10:04:01 BY MR. NORTH:
Q Have you seen 5322 before?
A Yes, I have.
Q What is this document?
A So this is the letter from FDA approving the IDE for the 10:04:15 EVEREST study. So giving Bard approval to conduct the EVEREST clinical trial.
MR. NORTH: Your Honor, at this time we would tender Exhibit 5322.
MR. LOPEZ: No objection, Your Honor.
10:04:27 THE COURT: Admitted.
(Exhibit 5322 admitted.)
MR. NORTH: Could we display, Your Honor?
THE COURT: Yes.
BY MR. NORTH:
10:04:39 Q In this application did the FDA limit the EVEREST study to

10:04:43 a specific number of institutions and patients?
A Absolutely. Every IDE is -- approval is limited to a certain number of institutions and subjects. So FDA limited the study to 15 institutions and 100 subjects.
10:05:03 Q Did Bard have any obligations to communicate with the FDA during the progress of the EVEREST study?
A Yes. As part of the IDE program, companies are required to submit -- if they observe any unanticipated adverse events, they have to submit that information to FDA. To the best of
10:05:25 my knowledge, there were no unanticipated adverse events. But they also have to submit periodic or annual reports to the FDA documenting the progress of the study. And then when the study's over, they have to submit a final report.
Q After Bard completed the EVEREST study, what did Bard do
10:05:45 next with regard to the G2?
A So Bard -- once the study was completed and the study report was finalized, Bard submitted a traditional 510(k) submission to FDA requesting approval to expand the indications from permanent to permanent plus retrievability.
10:06:09 MR. NORTH: If we could bring up Exhibit 5340, please.
BY MR. NORTH:
Q Do you recognize 5340?
A Yes. This is the 510(k) submission for the Recovery G2,
10:06:18 or just the G2 with the retrievable indications.

10:06:25 MR. NORTH: Your Honor, at this time we would tender Exhibit 5340.

MR. LOPEZ: No objection, Your Honor.

THE COURT: Admitted.

10:06:38 (Exhibit 5340 admitted.)

MR. NORTH: If we could turn to page 406.

Your Honor, could we display?

THE COURT: You may.

BY MR. NORTH:

10:06:49 Q During the course of the EVEREST study, were there some complications that had been observed in patients?

A Yes, there were.

Q Were those complications reported to the FDA in the 510(k) submission for the EVEREST study -- I mean, for the

10:07:06 retrievability indication.

A Yes, they were. There was a very lengthy clinical study report that was included in the 510(k), I think it was almost a thousand pages, and it included both summary information about the adverse events, like the table on the slide, and it

10:07:25 also included detailed information about individual adverse events.

MR. NORTH: Let's look at page 339 of this exhibit, please.

BY MR. NORTH:

10:07:42 Q Did Bard actually submit to the FDA the complete final

10:07:47 report from the EVEREST study?
A Yes, they did.
MR. NORTH: If we could turn to page 408.
And if we could display that chart, please.
10:08:14 BY MR. NORTH:
Q Did Bard provide the FDA with evidence or calculations of the complication rates found in the EVEREST study?
A Yes, they did. That's actually documented in this table.
Q And what did Bard report was the fracture rate in the
10:08:33 EVEREST study?
A So the fracture rate was 1.2 percent.
Q And what did Bard report was the migration rate in the EVEREST study?
A 12.2 percent.
10:08:46 Q And what did Bard represent was the penetration rate?
A 21.7 percent.
Q Did Bard also compare those or provide those to the FDA next to the SIR reported rates?
A Yes, they did.
10:09:04 Q What is your understanding of what the SIR reported rates are?
A So the Society for Interventional Radiology has published a paper that describes the rates of adverse events observed in the clinical literature and the ranges, and so this table
10:09:23 shows the ranges of adverse event rates in that SIR document.

10:09:29 It was published in 2003, and it compares the rates that Bard observed during the EVEREST study with the rates reported in the SIR paper.

Q Have you seen any evidence in your review of the FDA's 10:09:46 internal documents and the communications between the FDA and Bard, any evidence that FDA was concerned about the complications reported in the EVEREST study?

MR. LOPEZ: Well, I think that calls for kind of an opinion or a conclusion without a foundation. Calls for her 10:10:05 speculation about somebody else's concerns.

THE COURT: Overruled the way it's phrased.

THE WITNESS: So I believe that if FDA had -- had concerns about these complication rates that Bard was not able to answer, they would not have cleared the G2 for the 10:10:22 retrievable indications. So the fact that FDA eventually cleared the 510(k) demonstrates to me that FDA did not have any significant concerns about these adverse event rates.

MR. NORTH: If we could bring up Exhibit 5339, please.

10:10:42 BY MR. NORTH:

Q Do you recognize 5339?

A Yes. This is the SE letter, the substantial equivalence letter, where FDA is clearing the G2 for the retrievable indications.

10:10:57 MR. NORTH: Your Honor, at this time we would tender

Exhibit 5339.

MR. LOPEZ: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit 5339 admitted.)

MR. NORTH: Could we display?

THE COURT: You may.

BY MR. NORTH:

Q Did the agency -- looking at the first paragraph, did the agency find substantial equivalence to permit Bard to begin selling the G2 filter as a retrievable filter?

A Yes. It says that FDA has reviewed the 510(k) and determined that the device is substantially equivalent to the predicate device.

Q Did Bard submit any other 510(k) submissions to the FDA regarding the G2 filter?

A Yes. Bard submitted several additional 510(k)s for the G2 filter.

MR. NORTH: If we could bring up Exhibit 5354, please.

BY MR. NORTH:

Q What is 5354?

A So this is a Special 510(k) submitted by Bard to add an additional delivery kit for the G2 filter. So the original 510(k) was cleared with a certain kind of delivery kit, and then in this Special 510(k) bard is asking FDA to clear a new

route of -- a new way of accessing the patient, basically, to deliver the filter. There were no changes to the filter, it's just a new way to deliver it.

Q And by you saying new way of -- to deliver it, do you mean through the jugular vein as opposed to the femoral vein?

A Exactly. So this is for jugular subclavian access, whereas the original 510(k) was cleared for femoral access.

MR. NORTH: Your Honor, I would tender 5354.

MR. LOPEZ: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit 5354 admitted.)

MR. NORTH: Now, if we could look at 5353, please.

BY MR. NORTH:

Q Could you identify what 5353 is.

A Is this the correct exhibit?

This is --

Q No. Okay. You are absolutely correct.

A We've already seen this one.

Q Did Bard eventually receive a clearance letter from the FDA?

A Yes, they did.

Q Regarding the jugular approach G2?

A Yes, FDA did clear that 510(k).

MR. NORTH: If we could now look at 5361.

BY MR. NORTH:

Q Is this another 510(k) submitted regarding the G2?

A Yes. This is another 510(k) for -- once again, for some minor modifications to the delivery kit.

Q And what sort of modifications were those?

A They were modifications to the delivery kit. They didn't actually change the filter itself. So just modifications intended to make it easier to deliver the filter.

MR. NORTH: Your Honor, at this time we would tender Exhibit 5361.

MR. LOPEZ: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit 5361 admitted.)

MR. NORTH: And then if we can bring up 5362, please.

BY MR. NORTH:

Q Do you recognize 5362?

A Yes. But this is also for the wrong exhibit again. This is for the permanent -- the permanent G2 SE letter. Because you can see the limitation.

Q When is this dated?

A 2006.

Q Do you recall that the G2 was cleared for permanent use in 2005?

A Yes, it was.

10:15:26 Oh. I see. So I think I'm a little confused with the 510(k) numbers on here. It's hard to see on my screen.

So is this the same 510(k) number -- this is a 510(k) for the permanent G2 filter modification.

10:15:48 So let me just clarify this, because I got a little confused for a moment.

So if you recall, we had sort of bifurcated the G2. We had clearance for 510(k) for permanent indications, and meanwhile we're doing the clinical study for EVEREST. And

10:16:03 then, in the meantime, Bard submitted two Special 510(k)s to make modifications to those delivery systems for the permanent indications.

And the last 510(k) we looked at and this one are both for these minor modifications to the delivery systems

10:16:18 that were made while the EVEREST study was being conducted.

So I apologize, Richard, I was a little confused there are for a minute.

So this is the substantial equivalence letter for the second of those Special 510(k)s that were made to the G2

10:16:34 permanent while the EVEREST study was underway.

So I got a little confused there for a minute.

MR. NORTH: Your Honor, at this time we would tender 5362 into evidence.

MR. LOPEZ: No objection, Your Honor.

10:16:43 THE COURT: Admitted.

09:28:06 (Exhibit 5362 admitted.)

MR. NORTH: And let's go back, if we could, to 5353. I see I think I've seen the source of confusion.

THE WITNESS: Yes. I think that's what the issue 10:16:53 was too.

BY MR. NORTH:

Q Now that you see 5353, do you recognize what this is?

A Yes. So this is -- so this is once again for the permanent G2, this is the first Special 510(k) clearance 10:17:04 letter that the FDA issued where they've cleared the jugular subclavian delivery route for the permanent G2.

MR. NORTH: Your Honor, at this time we would tender 5353 into evidence.

MR. LOPEZ: No objection, Your Honor.

10:17:19 THE COURT: Admitted.

(Exhibit 5353 admitted.)

MR. NORTH: Can we display, Your Honor?

THE COURT: You may.

MR. NORTH: And if we could look at the first 10:17:26 sentence of the letter.

BY MR. NORTH:

Q Again, did the agency find the device under this Special 510(k) and the introduction of the jugular system a delivery system to be substantially equivalent?

10:17:44 A Yes, they did.

10:17:45 Q And did that permit the company to begin selling the jugular delivery system?
A Yes, it did.
MR. NORTH: If we could bring up 5373, please.
10:18:03 BY MR. NORTH:
Q Do you recognize 5373?
A So yes. So this one is in 2008. So this is the G2 Express. So Bard has now obtained clearance for retrievability. So we've got the G2 now, it's cleared for
10:18:18 permanent and retrievability. And now Bard is submitting a series of Special 510(k) submissions to make modifications to the delivery kit for the G2 with the retrievable indications. And this is one of those special 510(k)s.
Q And do you know what was different about the G2 Express?
10:18:37 A So this is also some modifications to the delivery kit with no changes actually made to the filter itself.
MR. NORTH: Your Honor, at this time we would tender 5373.
MR. LOPEZ: No objection, Your Honor.
10:18:51 THE COURT: Admitted.
(Exhibit 5373 admitted.)
MR. NORTH: If we could look at Exhibit 5368, please.
BY MR. NORTH:
10:19:02 Q And what is 5368?

10:19:10 A So this is FDA clearance letter for the Special 510(k) we were just talking about. When you look at it you'll see that that language, that limitation language is no longer there because FDA has approved -- has cleared the G2 for retrievable 10:19:27 indications at this point.

MR. NORTH: Your Honor, at this time we would tender 5368.

MR. LOPEZ: No objection, Your Honor.

THE COURT: Admitted.

10:19:35 (Exhibit 5368 admitted.)

MR. NORTH: May we display?

THE COURT: Yes.

BY MR. NORTH:

Q Again, looking at the first sentence, did the agency find 10:19:44 the application, the device to be substantially equivalent to the predicate device?

A Yes, they did.

MR. NORTH: If we could look 5379, please.

BY MR. NORTH:

10:20:12 Q And is this still another 510(k) regarding the G2 Express?

A Yes, it is. This is another modification to the delivery system for the G2 Express.

MR. NORTH: Your Honor, at this time we would tender 5379.

10:20:31 MR. LOPEZ: No objection, Your Honor.

10:20:33 THE COURT: Admitted.
(Exhibit 5379 admitted.)
BY MR. NORTH:
Q Did the FDA again clear this particular 510(k)?
10:20:40 A Yes, they did.
MR. NORTH: If we could look at Exhibit 5376.
BY MR. NORTH:
Q Is this the clearance letter for that application from the FDA?
10:20:52 A Yes, it is.
MR. NORTH: Your Honor, at this time we would tender 5376.
MR. LOPEZ: No objection, Your Honor.
THE COURT: Admitted.
09:28:06 (Exhibit 5376 admitted.)
MR. NORTH: Could we display, Your Honor?
THE COURT: Yes.
BY MR. NORTH:
Q And, again, did the agency find that this modification
10:21:09 made to the G2 Express was substantially equivalent to a legally marketed predicate device?
A Yes, they did.
Q Now let's turn to the Eclipse filter, finally.
Prior to submitting any application to the FDA for
10:21:30 the Eclipse filter, did Bard discuss the filter with the

10:21:34 agency?
A Yes, they did.
Q Did Bard also discuss other filter projects it was undertaking with the agency?
10:21:43 A Yes, they did. I reviewed minutes from a meeting between Bard and FDA where Bard described its sort of plans for a family of modifications to the filters that it was working on, including the Eclipse filter.
MR. NORTH: If we could look at Exhibit 5593.
10:22:17 BY MR. NORTH:
Q Are these the minutes that you referenced?
A Yes, they are.
Q Did you see evidence that Bard had discussed with the FDA the fact that it was attempting to develop caudal anchors?
10:22:42 MR. LOPEZ: Your Honor, I'm going to object if she's -- this is a document that's clearly hearsay. I think she's just going to regurgitate what's in the document.
THE COURT: I don't think the question is about the document.
10:22:50 Could you ask it again, though, to make clear you're not asking her what's in the document.
BY MR. NORTH:
Q Have you seen evidence that Bard communicated with the FDA that it was developing caudal anchors --
10:23:01 MR. LOPEZ: Same objection, Your Honor. Evidence

could be -- calls for her legal conclusion to determine whether or not this is considered evidence or not. It's hearsay.

THE COURT: What's your response on hearsay?

MR. NORTH: I'm not asking her for the truth of the matter asserted, just whether she's seen evidence of discussions on topics.

THE COURT: Objection is overruled.

THE WITNESS: So I have seen meeting minutes that describe -- that describe communications between Bard and FDA where Bard talked about its plans to develop a filter with caudal anchors.

BY MR. NORTH:

Q How would you characterize, as a regulatory specialist, the interactions Bard had with the FDA during this time frame 2008, 2009 regarding the various filter projects it had underway?

A I would say that Bard was very interactive with FDA. Usually what companies do is they develop a device, they submit it FDA, and FDA reviews it. It's not common for a company to come in to FDA with its sort of long-range product plans and describe the different products that it's contemplating and to lay that whole product strategy out in front of FDA.

Q What type of 510(k) did Bard eventually submit after these

10:24:33 discussions to the FDA regarding the Eclipse filter?
A So they submitted a Special 510(k).
Q What type of testing data does one typically provide to the FDA in a Special 510(k) application?
10:24:50 A So the testing that underlies a Special 510(k) is the same as a traditional 510(k). The only difference is that instead of actually providing the actual test reports, in a Special 510(k) companies can provide just a summary of the test reports.
10:25:07 MR. NORTH: Let's look, if we could, at Exhibit 5272.
BY MR. NORTH:
Q Do you recognize this document?
A Yes. This is the Special 510(k) for the Eclipse filter
10:25:20 system.
MR. NORTH: Your Honor, at this time we would tender Exhibit 5272, please.
MR. LOPEZ: No objection, Your Honor.
THE COURT: Admitted.
09:28:06 (Exhibit 5272 admitted.)
MR. NORTH: Could we display, Your Honor?
THE COURT: Yes.
MR. NORTH: If we could, let's turn to page 2, please.

10:25:42 BY MR. NORTH:
Q Does this generally indicate what sort of information Bard was providing the FDA regarding the Eclipse filter?
A Yes. This is a sort of typical table of contents for a
10:25:56 Special 510(k) submission.
Q Does it provide labeling?
A Yes. You can see that the appendices included the labeling for the predicate device, which was the device that was already marketed, the labeling for the subject device, and
10:26:14 then engineering drawings for the predicate device and the subject device so that FDA could understand what the differences are. And then something called DFMEA, which is a Design Failure Modes Effects Analysis.

MR. NORTH: If we could go back to the whole page.

10:26:35 BY MR. NORTH:
Q Under the tables, what sort of information was provided to the FDA?
A So what FDA's doing in this -- what Bard is doing in this table is helping FDA to understand what are the changes
10:26:47 between the device that's legally marketed and the new Eclipse.

So they've got a Table 1, where they're showing the differences between the filter that was previously cleared and the new filter.

10:26:58 They've got Table 2, where they're comparing the

10:27:03 delivery -- the femoral delivery system in the two devices.

Table 3, they're comparing the jugular delivery systems.

And Table 4, they're doing an overall comparison.

10:27:11 And so -- and these are basically comparing what the new device is to what the old device is.

And then in Table 7, they summarize the testing that they did in order to verify and validate the Eclipse.

MR. NORTH: If we could turn to page 35, please.

10:27:33 BY MR. NORTH:

Q What did Bard provide the FDA in terms of a risk analysis?

A So the fundamental basis of a Special 510(k) is I've got a legally marketed device where there's a presumption that the device -- that there has been demonstrated to be as safe and

10:27:50 effective as the predicate, and now I've made changes to it. And so when you make changes, you need to do a risk analysis and say I've made these changes, what new risks or changes to risks could that modification cause. And so that is documented in this DFMEA.

10:28:09 So in this, FDA is looking at the fact that Bard has said it's done a risk analysis, and then Bard's provided a table that summarizes what the major new risks or changes in risks are as a result of this modification.

And then Bard actually provided a copy of the actual

10:28:29 DFMEA in this submission, which is actually not required.

10:28:34 MR. NORTH: If we could turn to page 118 of this exhibit, please.

BY MR. NORTH:

Q And is this what you were just referencing?

10:28:44 A Yeah. This is the actual DFMEA.

MR. NORTH: Okay. If we could turn to or bring up Exhibit 5588.

BY MR. NORTH:

Q And what is this exhibit, Dr. Tillman?

10:29:03 A So this is the substantial equivalence letter where FDA is clearing the Eclipse filter system.

MR. NORTH: Your Honor, at this time we would tender 5588.

MR. LOPEZ: No objection, Your Honor.

10:29:14 THE COURT: Admitted.

(Exhibit 5588 admitted.)

MR. NORTH: Can we display, Your Honor?

THE WITNESS: You may.

BY MR. NORTH:

10:29:19 Q Dr. Tillman, is this the letter that allowed Bard to begin selling the Eclipse filter?

A Yes, it is.

Q And that was dated what?

A December 15th, 2009.

10:29:33 THE COURT: All right. We're going to break at this

10:29:35 time. We will resume, ladies and gentlemen, at 10:45 and excuse the jury.

(The jury exited the courtroom at 10:29.)

MR. LOPEZ: Your Honor, I didn't want to call you
10:30:06 while the jury -- there's going to be an issue I'm going to need to talk about before I start my cross. Should we wait until we resume and then do a sidebar? Do you want us to come back early and --

THE COURT: How much longer do you have, Mr. North?

10:30:17 MR. NORTH: Probably about 20 to 30 minutes, Your Honor.

MR. LOPEZ: I can do it at sidebar, Your Honor, before I start my cross.

THE COURT: Let's just do that. All right.

(Recess taken from 10:30 to 10:49. Proceedings resumed in open court with the jury present.)

THE COURT: Thank you. Please be seated.

Sorry for the delay, ladies and gentlemen. We had to turn off the sound system and turn it back on to get rid of
10:50:45 that beeping.

You may proceed, Mr. North.

MR. NORTH: Thank you, Your Honor.

If we could display Exhibit 5588 again.

THE COURT: You may.

BY MR. NORTH:

Q Dr. Tillman, before the break I think I was confused as to what this letter is. Is this the actual clearance letter for the Eclipse?

A No. Actually, this is a request for additional information.

Q If we could look at the second paragraph there. What did the agency indicate to Bard regarding its Eclipse 510(k) submission?

A So in the 510(k) submission, Bard had done its failure mode analysis and determined that a certain subset of testing was necessary: Corrosion resistance, cyclic fatigue, and arm fatigue testing. However -- and Bard had determined that that was the testing that it needed to.

FDA came back and said, well, you haven't done radial force testing, migration/clot trapping testing or tensile strength testing, and that this was information because FDA believed that electropolishing could affect the strength of the legs.

So here is FDA sending this letter to Bard asking them to provide the results of additional testing.

MR. NORTH: If we could bring up Exhibit 5486, please.

BY MR. NORTH:

Q Did Bard actually provide a supplemental response to the

FDA?

A Yes, they did.

Q And was that in response to the FDA's request for various additional information?

A Yes, it was.

MR. NORTH: Your Honor, at this time we would offer 5486.

MR. LOPEZ: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit 5486 admitted.)

MR. NORTH: Could we display, Your Honor?

THE COURT: Yes.

MR. NORTH: If we could turn to page 7, please.

BY MR. NORTH:

Q If we could look at the first paragraph.

How did Bard respond to FDA's inquiry concerning tests that had not been submitted initially?

A So Bard explained that when they made the changes, they performed what's called this design failure modes and effects analysis to understand what the impact of those changes might have been on the risks presented by the device and on the failure modes. And as a result of that, they determined they needed to do a certain kind of testing. And they say here that although this analysis did not identify radial force testing, migration/clot trapping or filter tensile strength

10:53:33 testing, that a different analysis they did, which is a process failure modes and effects analysis, which is more about sort of the manufacturing process, did require them to do that testing, and so they had actually done it.

10:53:46 And so in this response they're basically providing a summary of the additional testing that they'd done consistent with what FDA was asking for.

Q So had Bard, in fact, done all three tests the FDA had requested information about?

10:54:05 A Yes. They had done the testing, they simply had not provided it in the original 510(k) submission.

Q If we could look at the bottom of page 7.

Did Bard then describe for the FDA the radial force testing that had been previously performed on the Eclipse?

10:54:24 A Yes. So in this response they basically summarized the testing that they did for each of those areas, including, for example, here, the radial force testing.

MR. NORTH: If we could turn to page 8, please.

BY MR. NORTH:

10:54:42 Q Did Bard describe for the FDA the migration/clot trapping testing that had been performed on the Eclipse filter?

A Yes, they did. They basically described the fact they did migration/clot trapping and that the result of that testing showed that the performance was no different from that of the

10:55:01 predicate device.

10:55:06 MR. NORTH: And then if we could turn to page 9.
BY MR. NORTH:
Q Did Bard describe for the FDA and provide the agency with data on the filter tensile strength testing it had already
10:55:17 performed on the FDA -- I mean on the Eclipse?
A Yes. So Bard basically described it had conducted this testing and that the results of this testing showed there was no difference between the performance of this device and the predicate device.
10:55:34 Q After Bard submitted these responses to the FDA's questions, did the FDA ask for any additional testing regarding the Eclipse filter?
A No. FDA determined that this information was sufficient since they didn't ask for any additional information.
10:55:49 MR. NORTH: If we could bring up Exhibit 5273, please.
BY MR. NORTH:
Q Now, could you tell us what 5273 is?
A Yes. So now this is the actual substantial equivalence
10:56:03 letter for the Eclipse filter.
MR. NORTH: Your Honor, we would tender for admission 5273.
MR. LOPEZ: I'm sorry, Your Honor. No objection.
THE COURT: Admitted.
10:56:14 (Exhibit 5273 admitted.)

MR. NORTH: Could we display, Your Honor?

THE COURT: Yes.

BY MR. NORTH:

Q So now that the record's clear, on what date did the FDA clear the Eclipse filter?

A January 14th, 2010.

Q And what was the predicate device, again, for the Eclipse?

A It was the G2 filter.

Q And did the agency, in that first sentence, find the Eclipse filter to be substantially equivalent to the G2?

A Yes, they did.

Q Now, did Bard eventually submit an additional 510(k) submission to the FDA regarding the Eclipse device?

A Yes, they did.

Q What was the second 510(k) for?

A So Bard determined that it wanted to provide a patient brochure to provide information about the Eclipse filter and they decided that although it may not have been required to submit a Special 510(k) to FDA, that they wanted to get FDA's feedback on the patient brochure and so they submitted a Special 510(k) for that.

MR. NORTH: Let's look at Exhibit 5586 if we could, please.

BY MR. NORTH:

Q What is this document, Dr. Tillman?

10:57:45 A So I -- given the date, I believe this is the Special 510(k) for the -- to add the patient brochure to the Eclipse filter.

MR. NORTH: Your Honor, at this time we would tender 5586.

10:57:58 MR. LOPEZ: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit 5586 admitted.)

MR. NORTH: Then if we can bring up 5589, please.

10:58:06 BY MR. NORTH:

Q What is 5589?

A So this is another substantial equivalence letter from FDA saying that the Eclipse filter with the patient brochure was found substantially equivalent.

10:58:26 MR. NORTH: Your Honor, at this time we would tender 5589.

THE COURT: Any objection?

MR. LOPEZ: No objection, Your Honor.

THE COURT: Admitted.

09:25:03 (Exhibit 5589 admitted.)

MR. NORTH: Could we display, Your Honor?

THE COURT: Yes.

BY MR. NORTH:

Q And what was the date of the clearance of the filter with

10:58:43 the patient brochure Bard had prepared?

10:58:46 A June 25th, 2010.
Q Is this the second time that the agency has cleared as substantially equivalent the Eclipse filter?
A Yes, it is.
10:59:07 Q You told us, I believe yesterday, during the course of your consulting work you assist medical device manufacturers in the preparation of labeling for devices?
A Yes, I do.
Q During your years at the FDA, did you yourself actively
10:59:21 review labeling for devices?
A I spent quite a bit of time reviewing labeling. Yes.
Q And based on the information you have reviewed in this case, how would you characterize the information that Bard provided to doctors in the Eclipse instructions for use?
10:59:40 A So I believe the labeling was consistent with FDA's guidance document.

I believe that it was consistent with what FDA expected for IVC filters, based on the communications that FDA had regarding the changes it actually asked FDA to make on the
11:00:00 patient brochure.

I think it is consistent with the competitor labeling that I have reviewed. So I have reviewed other companies' IVC filter labeling, and it's my opinion this labeling is consistent with that as well.
11:00:15 Q Over the years in your review -- well, in your review of

11:00:18 the regulatory history for Bard's family of retrievable filters, did you see evidence on occasion that the FDA requested Bard to make changes to the instructions for use?

A Yes. I believe there were quite a few occasions where FDA

11:00:37 asked Bard to make changes to its labeling.

Q Did you see any evidence that the FDA asked Bard to include complication rates as compared to other manufacturers' filters in the --

MR. LOPEZ: Objection, Your Honor. Sorry. 403,

11:00:52 foundation, 602.

THE COURT: Overruled.

THE WITNESS: So I did not see any evidence in the documents that I reviewed that FDA requested that Bard include any kind of comparative rate information in their

11:01:09 labeling.

BY MR. NORTH:

Q Do you have an opinion, Dr. Tillman, as to whether it would have been appropriate for Bard to include comparative complication rate data in its IFU?

11:01:23 A So in my experience, the only time that information is appropriate is if you -- if the company has done a clinical study, and this is often done for PMA devices where you study a company's device and a competitor device, and then you report the adverse event data that was seen for both devices

11:01:41 in your clinical study summary in your labeling. But that's

11:01:46 only for PMA devices usually, and that's only for devices where you've actually conducted a clinical study where you know what the rates are.

I think if you're talking about including comparative 11:01:56 rate information based on the MAUDE database, I don't believe it would be appropriate to include that information in the labeling because I don't believe that the MAUDE database provides data of sufficient quality to be able to draw any conclusions about comparative rates.

11:02:13 MR. NORTH: If we could bring up Exhibit 7795, please.

BY MR. NORTH:

Q Do you recognize Exhibit 7795?

A Yes. This is a screen shot of the FDA -- the portal -- 11:02:34 electronic portal into FDA's MAUDE database.

MR. NORTH: Your Honor, at this time we would tender Exhibit 7795.

MR. LOPEZ: No objection, Your Honor.

THE COURT: Admitted.

11:02:52 (Exhibit 7795 admitted.)

BY MR. NORTH:

Q So what does the FDA say about the limitations with regard to --

MR. NORTH: I'm sorry. Could we display, 11:03:06 Your Honor?

11:03:08 THE COURT: Yes, you may.

BY MR. NORTH:

Q What does the FDA say generally about the limitations?

A So there's a number of bulleted limitations listed below
11:03:19 the search engine, and some of the limitations are about the fact that it's limited to adverse events reported within the past ten years.

I think more importantly for this conversation we're having here is that MDR data alone cannot be used to establish
11:03:35 rates of events, evaluate a change in rates of events over time, or compare event rates between devices.

Q Based upon those limitations, do you believe it's appropriate to use the MAUDE database to compare -- provide data to doctors regarding comparative rates?

11:03:59 A No, I don't believe it would be appropriate to use the MAUDE data in that way.

Q Generally speaking, are manufacturers permitted to include flawed or incomplete data in its warnings?

A No. The information that's in manufactures' labeling
11:04:25 needs to be based on valid scientific evidence, and I would not consider MAUDE data to constitute valid scientific evidence for the purpose of establishing adverse event profiles.

Q Dr. Tillman, as a part of your work in this case, have you
11:04:39 looked at the instructions for use for some other inferior

11:04:45 vena cava filters manufactured by different companies?
A Yes, I have.
MR. NORTH: If we could bring up Exhibit 7787, please.
11:04:57 BY MR. NORTH:
Q Do you recognize --
MR. NORTH: Go to the second page, if we could.
BY MR. NORTH:
Q Do you recognize this particular document?
11:05:03 A Yes. This is the instructions for use for the Cordis OptEase IVC filter.
MR. NORTH: Your Honor, at this time we would tender Exhibit 7787.
MR. LOPEZ: Objection, Your Honor. Relevance and
11:05:17 hearsay.
THE COURT: Overruled on relevance.
What's your response on hearsay?
MR. NORTH: Your Honor, it's not being offered for the truth of the matter asserted as to any statement within
11:05:27 there.
MR. LOPEZ: I'll add 403 to my objection, Your Honor.
THE COURT: All right. I'm going to overrule 403.
I will admit this exhibit, but with the instruction
11:05:38 to the jury similar to one I gave before, which is

Exhibit 7787 is not being admitted to the show the truth of what it is saying. The facts stated in the document are not being offered as true to you by this document. Rather, it's simply to show what is in the document for purposes of the witness's testimony.

And with that instruction I'll admit 7787.

(Exhibit 7787 admitted.)

MR. NORTH: May we display the document?

THE COURT: Yeah.

MR. NORTH: Go to the first page so the jury can see that, Mr. Russell.

Then if we could turn to page 8, please.

BY MR. NORTH:

Q What does this document generally show on page 8?

A So there's information in here about potential complications that may be experienced with the device. That's in section 6.

And then in section 7 it's a summary of the clinical study that was conducted to support the OptEase filter.

Q And does that discussion continue over onto pages 9 and 10 about the clinical experience with the OptEase filter?

A Yes, it does.

Q At any point in this IFU, in those sections or in any other section, is there any mention comparing complication rates between the Cordis filter and other competitive filters?

11:07:05 A Not to the best of my knowledge, no.

MR. NORTH: Okay, if we could look at Exhibit 7771.

BY MR. NORTH:

Q Could you identify for us what 7771 is.

11:07:23 A So this is the instructions for use for another vena cava filter. This is the B Braun VenaTech.

Q And did you review this particular brochure or IFU as part of your work in this case?

A Yes, I did.

11:07:42 MR. NORTH: Your Honor, at this time, subject to same limitation, we would offer 7771.

MR. LOPEZ: Same objections, Your Honor, as I made to the prior exhibit.

THE COURT: All right. Those objections are

11:07:50 overruled.

But 7771 comes in with the same instructions, that you're not to consider it for the truth of what is asserted in the document itself.

(Exhibit 7771 admitted.)

11:08:03 MR. NORTH: Could we display, Your Honor?

THE COURT: You may.

BY MR. NORTH:

Q So this is the instructions for use for the Braun VenaTech IVC filter?

11:08:14 A Yes, it is.

11:08:15 MR. NORTH: If we could turn to page 5, under Potential Adverse Effects.

BY MR. NORTH:

Q In that section or any other section, did you see any
11:08:33 mention of comparative rate -- complication rate information?

A No, I did not.

Q In your experience, Dr. Tillman, have you ever seen a manufacturer of any medical device include comparative rate information based on MAUDE data?

11:08:52 A No, I have never seen medical device labeling include that information.

Q Dr. Tillman, during the course of your work in this case, have you seen any labeling or promotional materials by Bard that, in your opinion, inappropriately reflected risk
11:09:16 information?

A No. None of the Bard labeling materials that I reviewed, in my opinion, inappropriately represent the risk information.

Q Have you seen any evidence during your work in this case that in submitting 510(k) applications to the FDA and in
11:09:36 responding to the FDA's questions, did you see any occasion where Bard did not appropriately disclose information to the agency as a part of the 510(k) process?

A To the best of my knowledge, Bard provided complete and appropriate responses to FDA's questions and the information
11:09:57 in the 510(k) was consistent with FDA's guidance documents and

what I would have expected to see, in my professional opinion, in an IVC filter 510(k) from that period of time.

Q Does the evidence you have reviewed in this case lead you to any opinion as to whether the FDA conducted a risk/benefit analysis regarding IVC filters in general?

A I believe that in reviewing the 510(k)s and in clearing the Bard IVC filters that FDA was making a determination that the benefits of the device outweigh the risks because I think that is a fundamental part of making a substantial equivalence determination.

Q Dr. Tillman, do you hold all of the opinions you have expressed yesterday and today to a reasonable degree of certainty as an expert in the field of regulatory affairs?

A I do.

MR. NORTH: Thank you. That's all the questions I have.

THE COURT: All right. Thank you.

Mr. Lopez.

MR. LOPEZ: May I proceed, Your Honor?

THE COURT: You may.

MR. LOPEZ: Thank you, Your Honor.

C R O S S - E X A M I N A T I O N

BY MR. LOPEZ:

Q Dr. Tillman, hi. Good morning.

A Good morning.

11:11:15 Q Now, I'm harking back to yesterday and we were talking about substantial equivalence and how the risk/benefit sometimes doesn't have to be the same between a predicate device and a device that's going through 510(k). Do you
11:11:32 remember that discussion? I think you used an exhibit to talk about that. Recall that?

A Yes, I do.

Q Now, have you seen any evidence in this case or any statement by Bard or FDA that the design changes of Bard
11:11:47 filters that were going to become retrievable filters increased the risk of complications over permanent filters?

A So are you talking about a particular filter or just --

Q Any evidence where Bard said to the FDA, by the way, we're making this change to the design of our filter but it may not
11:12:11 be quite as safe as our predicate device, the Simon Nitinol filter. Did you see anything like that?

A So, no, I didn't see any evidence that the retrievable filters were less safe and I didn't see any evidence that Bard made that statement to the FDA.

11:12:27 Q Did FDA ever authorize or approve any Bard filters that received a retrievable indication that they did not have to be at least as safe and effective as the Simon Nitinol filter?

A So when FDA cleared the 510(k)s for the Bard filters, they were finding that a particular device was substantially
11:12:54 equivalent to whatever the predicate. So the Simon Nitinol

filter was the predicate for the original Recovery, so the FDA was determining that it was as safe and effective as Simon Nitinol.

Q I guess maybe a different way to ask it was did FDA tell Bard in any document that the risk/benefit profile of its retrievable filters could be different than the Simon Nitinol filter? Yes or no?

A So there wouldn't have been an opportunity for FDA to make that kind of a statement to Bard.

Q Did Bard ever tell doctors that the risk/benefit profile of our retrievable devices is going to be different than our permanent device, the Simon Nitinol filter?

A So I've not reviewed all of Bard's communications with doctors. But I don't believe that Bard ever made that statement to doctors. But I'm not sure what the basis of that statement would be.

Q Is it fair to say that doctors to whom Bard filters were being sold would have had the expectation that those filters would have been at least as safe and effective as the Simon Nitinol filter?

A I don't believe that the doctors necessarily had any expectations about whether the Eclipse filter was as safe and effective as the Simon Nitinol filter.

Q Doctor, do you remember having your deposition taken on August 4 of 2017?

11:14:26 A I certainly do remember that, yes.
MR. LOPEZ: Could you show Dr. Tillman page 335 of that deposition, Gay.
MS. MENNUTI: Apologize. What deposition?
11:14:43 MR. LOPEZ: I'm sorry. It was the August 4, 2017, deposition. Page 335.
BY MR. LOPEZ:
Q See line 3, Dr. Tillman, where you state that, "Yes, I think it's fair for doctors to expect that the Recovery filter
11:15:06 be as safe and effective as the Simon Nitinol filter."
A And I think that's what I just said. The Simon Nitinol filter was the predicate device for the Recovery, so there is an expectation it be as safe and effective as the Simon Nitinol filter. I think for subsequent Bard filters,
11:15:23 I'm not sure that that is an appropriate statement to make.
Q Now, the subsequent Bard filters that had permanent -- all had permanent indications as well as eventually got retrievable indications. True?
A So certainly the G2 and the Eclipse filters have both
11:15:41 permanent and retrievable indications, yes.
Q Did FDA ever tell Bard that they did not -- as a retrievable filter that those filters did not need to perform as safely and effectively as the Simon Nitinol filter?
A So, once again, that's not a communication --
11:16:00 Q I know. I'm just asking if that happened, that's all.

11:16:02 A Well, no, but there wouldn't have been any reason for FDA to do that.
Q Did Bard tell doctors that if you're going to use any of our filters that have the option to be retrieved as a
11:16:15 permanent filter, that that optional filter's not going to be as safe and effective as a Simon Nitinol filter as a permanent device?
A I'm not sure I understand your question.
Q Well, let me ask you this: Did Bard tell anybody that
11:16:30 their safety profile of any their optionally retrievable filters was going to be different than the Simon Nitinol filter?
A As far as I know, Bard did not tell anybody that. But I'm not aware of any evidence demonstrating that there are
11:16:44 significant differences in the performance.
Q Now, at the very end, Mr. North asked you some questions about risk/benefit. You haven't done your own risk/benefit analysis of any Bard filter, have you?
A No, I have not.
11:16:58 Q And you're not giving an opinion today on what a reasonable doctor could or should expect Bard to share with them about the risk and benefits of their filters. True?
A That's right. I can't make any opinions about what a reasonable doctor would expect.
11:17:12 Q And through all of the materials you went through

11:17:15 regarding FDA letters back and forth, companies like Bard cannot suggest -- I'm sorry. Bard cannot suggest that any of those devices have been approved by FDA as being safe and effective. True?

11:17:31 A That is correct. A 510(k) is only cleared and it's only been shown to be as safe and effective as the predicate device.

Q And FDA regulations require that all information contained in a 510(k) application must be truthful, accurate, and that

11:17:46 no material fact has been omitted. True?

A That is correct.

Q In other words, if -- you have to provide both favorable and unfavorable testing that might affect the substantial equivalence profile of a predicate -- I'm sorry, a 510(k)

11:18:04 device. True?

A So you have to provide all material information, whether it's favorable or unfavorable.

Q Now, you did not -- I think you testified at your deposition that your job when you were hired by Bard's lawyers

11:18:17 was not to audit the documents in the depositions to see if there was anything that Bard may not have provided to FDA. True?

A Yes. So when I made that statement, I was differentiating between my role as an expert versus when I'm hired by

11:18:35 companies to do mock audits or investigations.

11:18:39 Q Now, you also testified you were given access to a lot of documents and depositions; right?
A Yes, I was.
Q First time, you remember, I took your deposition, 2014, all of the materials you received at that time was provided to you by the lawyers; right?
A So all of the material that -- Bard material that I received even to now has been provided to me by the attorneys. I don't have the access to Bard materials other than what's publicly available on my own.
Q Now, you know who Dr. Asch is; right?
A I know who Dr. Asch is, yes.
Q I think you told us at your last deposition that you asked the lawyers for Bard whether or not there was anything in Dr. Asch's deposition of 2016 that you should read for purposes of making your -- rendering an opinion, and they told you you didn't need to see Dr. Asch's deposition. True?
A I think you're mischaracterizing what I said.
Q Did you say that? Did you say that -- did the lawyers tell you you did not need to read Dr. Asch's deposition?
A No. What happened -- as I explained to you before, there are a lot of depositions, and I went through the list of depositions with the attorneys and I had already read one of Dr. Asch's depositions and I asked, is there anything new relevant to FDA regulations in this new deposition that I need

11:19:59 to look at, and they told me they thought that there wasn't anything significantly different.

MR. LOPEZ: Can I have page 62, Gay, please, of Dr. Tillman's 2017 deposition.

11:20:17 Line 9.

BY MR. LOPEZ:

Q "And the same would hold true for Dr. Murray Asch. You read Dr. Asch's deposition taken in January of 2011, but you knew there was a deposition taken in 2016; right?"

11:20:32 "Answer: I would have seen it on the list."

Next question: "You had discussion with counsel about the fact that there was a 2016 deposition and you asked, is there really any reason

11:20:47 for me to read his 2016 deposition?

And they said No."

"Is that essentially what happened?"

"Essentially. It may not have been those exact words but yes."

11:20:55 And how about Dr. David Ciavarella. Do you know who Dr. David Ciavarella is?

A Yes, I do.

Q And you were not provided with Dr. David Ciavarella's deposition that was taken in 2013. True?

11:21:09 A So I would say that I -- it's not that I wasn't provided

it, it was that I did not ask to see it.

Q Okay.

MR. LOPEZ: Could we have page 61 of that same deposition, Gay, please.

Page 61, line 6.

BY MR. LOPEZ:

Q "And the process then went to" --

MR. LOPEZ: Your Honor, can I display this to the jury, please? It's Exhibit --

THE COURT: Is this a deposition transcript?

MR. LOPEZ: Yes, Your Honor.

THE COURT: It's not in evidence. You can't -- it can't be displayed. You can use it for impeachment purposes in reading it, but you can't display it to the jury.

BY MR. LOPEZ:

Q "Question: And the process then went to is there anything in Dr. Ciavarella's 2013 deposition that I need to review for purposes of rendering my opinion?"

And you were told no.

"Answer: Is there -- there are really -- are there really any significant new or different issues in that that were important for my opinion?"

Correct.

You asked that and they told you you didn't need to read it; right?

11:22:14 A Yes. I asked them whether there was -- given that I had already read one of his depositions, whether there was anything additional in this new deposition that was relevant to the types of opinions I was presenting, and I was told no.

11:22:30 Q Do you know what Dr. Asch's opinion is about the manner in which his study was used and described in the permanent 510(k) of the Recovery filter?

A As I sit here today, I can't tell you what Dr. Asch's opinions are.

11:22:51 Q And if the manner in which that was represented in the 510(k) application was not truthful and accurate, what are your opinions about that?

A So I don't -- I think the data stand or their own. Dr. Asch was the investigator on the clinical study that was

11:23:10 used to support the Recovery filter, and those data were provided to FDA. So I'm not sure what Dr. Asch's opinions about the fact that those data could or could not support a 510(k) has to do with anything about FDA's determination.

Q I'm sorry. Asked a bad question.

11:23:27 My question should have been, wouldn't it have been in violation of federal regulations had Bard misrepresented the conclusions and findings of Dr. Asch's retrievability study?

A It would depend on what you mean by "misrepresenting."

11:23:45 Q It wasn't truthful and wasn't accurate.

11:23:47 A You would have to be more specific.
Q If it just -- generally, if in fact as it's represented in the 510(k) application it was not truthful and accurate, that would be a violation of 510(k) regulations. True?
11:24:03 A So the material in 510(k) has to be truthful and accurate. And so if there's information in a 510(k) that's not truthful and accurate, then that would be a violation.
Q Now, the bottom line is that Bard doesn't need the FDA to tell it to do a long-term study, does it?
11:24:24 A Bard certainly needs to be doing what it needs to do regardless of what FDA tells it. I would agree.
Q If internally they have risk analysis, they have done some of their own analysis of materials they have that they haven't shared with anybody, and it was appropriate for Bard to do a
11:24:40 clinical trial in the interest of patient safety, Bard should do that trial; right?
A I certainly think that patient safety should be first and foremost on the mind of any medical device manufacturer, yes.
Q Now, let's talk a little bit about you were at the FDA
11:25:04 until I think 2010?
A That's correct.
Q And then you went to work for Medtronic; right?
A No, no. Microsoft.
Q Microsoft. I'm sorry.
11:25:12 While you were at FDA, you often got approached to

work for industry; right?

A Not often. Occasionally people would approach me about whether I was interested in making a career move.

Q Well, I asked you at your deposition whether companies sought out your employment and you testified there were quite a few of them. Is that still accurate?

A Well, over 17 years, you know, I would say I was approached on an occasional basis. So perhaps quite a few. But it wasn't like it was happening every day.

Q Okay. And you actually were hired by the lawyers that represent Bard; right? You were hired -- I think you told us your client here is really the lawyers that hired you.

A Right. Remember, so I'm an employee of a company and so the -- Bard is a client of my company. Yes. Bard's lawyers are -- I'm sorry. Bard's lawyers are a client of my company.

Q And most of your clients, your paying clients, are either pharmaceutical or medical device companies?

A Yeah, the vast majority of the work I do is for pharmaceutical or medical device companies.

Q And you have also been hired by Mr. North's firm to work on the TVM litigation involving Bard; right?

A The?

Q TVM.

A Oh, transvaginal mesh. Yes, I also do expert witness in that space.

Q And can you estimate how much money you've billed for your time and working with the Nelson Mullins firm on both Bard and TVM cases?

MR. NORTH: Objection, Your Honor. 402 as to other litigation.

THE COURT: Overruled.

THE WITNESS: So as I mentioned yesterday, about 15 percent of my work is litigation work. And then I can't answer that directly because, remember, I get paid a salary. So my salary doesn't directly reflect what my company bills for my time.

BY MR. LOPEZ:

Q All I'm asking is for an estimate of how much money that you've billed the Nelson Mullins firm since 2000- -- whenever you started working on TVM and Bard.

A How much my company --

Q TVM and IVC cases.

A I'm sorry, do you mean how much my company has billed them?

Q Yes. Yes.

A I am an engineer; I don't like to give imprecise numbers. But I would say perhaps somewhere around $200,000. Perhaps.

Q And that's just -- that's just a small part of the money you earn working for or on behalf of either pharmaceutical or medical device companies. True?

11:27:49 A Once, again, that money does not come to me. That is the money my company makes. I'm paid --

Q I understand.

A -- salary --

11:27:55 Q You've explained that. I just want to know how much you billed. Through your work, small percentage of what you described that you got paid for working on Bard -- for Mr. North's firm, most of that -- the rest of that comes from working for pharmaceutical and medical device companies;

11:28:13 right? Can you just answer that yes or no?

A I'm sorry, I'm not sure I understand the question.

So, yes, I've already said that I work for medical device and pharma companies. They pay my company for my time and my company pays me a salary.

11:28:28 Q By the way, I can't go through all those document, I just don't have time. We have limited time. So I notice some of the names on the interactions that you showed us. One was Kennell, Ms. Kennell.

A Lisa Kennell, yes.

11:28:44 Q She's not a doctor; right?

A No. She's a microbiologist.

Q And I think Jenny Liu was another. I think she's an RN; correct?

A I believe Jenny Liu is a nurse, yes.

11:28:55 Q Would you agree that, for the most part, that people that

11:28:59 are reviewing materials with the 510(k) -- that are going through a 510(k) process are what you would call nonclinical people?

A So Jenny Liu is a nurse, so I would consider her a

11:29:14 clinical person. On the premarket side, most of the lead reviewers on 510(k)s are engineers and scientists, like myself. But if there's clinical data in the submission, there is always a medical officer that reviews the clinical data.

Q You were asked at your deposition, "Would you agree that

11:29:32 the primary reviewers of new medical devices that are being submitted under a 510(k) are more often than not nonclinical individuals at FDA?"

And your answer was, "Correct."

Is that still your answer today?

11:29:44 A Yes. That's the same answer I believe I just gave.

Q Now, if a new device is cleared through the 510(k) process but does not perform as represented to and cleared by FDA in a 510(k) submission, it is considered adulterated. True?

A So a device is considered adulterated if it's not

11:30:09 performing in accordance with its specifications.

Q Thank you.

Now, did you do an analysis of Bard's complaint files, complaint records?

A No, I did not do an independent analysis of Bard's

11:30:29 complaint files.

11:30:30 Q And you talked about the Dear Doctor letter that was -- that Bard had sent regarding the Recovery filter?
A Yes.
Q And you're saying that that letter appropriately
11:30:41 represented what was going on at Bard at the time?
A I believe that the information in that letter was consistent with -- based on the information I reviewed, with what Bard was observing about the Recovery filter at the time.
Q Do you have any idea the type of catastrophic injuries
11:31:00 that were caused by the Recovery filter when it was on the market?
MR. NORTH: Objection, Your Honor. 402 and 403.
THE COURT: As worded, I don't think it's a violation of any prior ruling or irrelevant or subject to
11:31:22 403, so I'm going to overrule the objection.
BY MR. LOPEZ:
Q You have no --
A I'm sorry, I lost the question.
Q The question is simply this: You weren't provided with
11:31:32 data, actually information, about the type of catastrophic injuries caused by the Recovery filter before you made your determination that the information in the Dear Doctor letter was appropriate. True?
A No, I don't agree with that. I very much reviewed
11:31:46 internal Bard documents and health hazard evaluations that

11:31:50 talked in detail about the kinds of events that Bard was seeing with the devices.

Q So your testimony about the appropriateness of the Dear Doctor letter had something to do with your review of, like, 11:32:01 health hazard evaluations that specifically described the type of events that were happening as a result of people getting the Recovery filter?

Can you answer that yes or no?

A So certainly all of the information that I reviewed bears 11:32:18 on my opinion that the Dear Doctor letter was consistent with Bard -- what Bard was observing.

Q So you saw everything that you needed to see?

A I certainly did not see everything and I have never said I've seen everything. However --

11:32:35 Q Now, the Dear Doctor letter mentions death, doesn't it?

A I believe so, although I'd have to see it to be certain.

Q Okay. Assuming it says death in the Dear Doctor letter, were you provided with data or any adverse event data that relates to death while the Recovery filter was on the market?

11:32:57 A So, once again, I reviewed health hazard evaluations and other internal Bard documents relating to the events that Bard was observing about the filter.

MR. LOPEZ: Your Honor, I'd like a sidebar on this. I'd like to go into different areas that have been affected 11:33:14 by a motion.

11:33:14 THE COURT: All right, let's have a sidebar.

You can stand, ladies and gentlemen.

(Bench conference as follows:)

MR. LOPEZ: Your Honor, there's a couple documents. 11:33:33 One of the documents referenced death that he offered into evidence. I can't remember which one it was. I think it had to do with the Dear Doctor letter.

The Dear Doctor letter, she's saying it was appropriate in telling doctors what happened with respect to 11:33:45 the Recovery filter. It doesn't. It hardly scratches the surface about what was really going on with the Recovery filter. That's number one. I can't cross-examine her on that. I have not had an opportunity to fairly cross-examine her on something that he made a big point on.

11:34:06 THE COURT: When you say he made a big point --

MR. LOPEZ: I'm sorry. Mr. North.

THE COURT: Big point of what?

MR. LOPEZ: The fact that Bard went the extra step and told doctors what was going on with their Recovery 11:34:16 filter, they were actually warning doctors and showing doctors what was going on in the Dear Doctor letter. They didn't. There's no way, if you look -- I mean, it does not tell the true story about what was going on with the Recovery filter. That's number one.

11:34:31 Number two, I haven't asked her this question yet,

but there's an issue about whether or not this was inappropriate -- she said it was a very appropriate predicate device. I've got to be able to ask her whether or not under the circumstances of the Recovery's history, whether or not it was appropriate, if whether FDA regulations allowed them to use that type of predicate device.

It says you're supposed to use the most appropriate predicate, and some of the testimony's coming up, she's testified to it already in deposition, that if a device is adulterated, it's not being legally marketed. I've got to be able to explore that fully.

If you've got 16 deaths compared to Simon Nitinol that had none, you're not being legally marketed. I can't scratch the surface with that. I mean, it has to be -- I mean, it just has to be a fair cross with respect to whether or not that was an appropriate predicate.

If Recovery's not an appropriate predicate, then G2's not on the market. If G2's not on the market, Eclipse's not on the market. That's a cascade --

THE COURT: I understand that argument. We're keeping the jury waiting, so don't repeat arguments you've made before. You've made that one, so I understand it.

MR. LOPEZ: Okay, but I'm just telling you -- okay. That's it.

MR. NORTH: First of all, Your Honor, I do not

11:35:52 believe I asked her for, as I recall, an opinion as to the adequacy of --

THE COURT: I want you to hear this because I want you to respond to it.

11:36:00 MR. NORTH: -- to the adequacy or sufficiency of the Dear Doctor letter.

My questions with regard to the Dear Doctor letter had to do with did they show it to the FDA; did the FDA look at it. Just the fact of the communication --

11:36:17 MR. LOPEZ: Can I get some water real quick?

THE COURT: Do you remember the number of the Recovery filter Dear Doctor letter.

MR. NORTH: I didn't introduce it, Your Honor.

THE COURT: You didn't identify it?

11:36:33 MR. NORTH: No. Oh, I know. I got one out. Let me run and get it.

It's in evidence.

THE COURT: Hold on just a minute.

I think what was admitted was document 6075 --

11:37:05 MR. NORTH: Which is right here --

THE COURT: -- which are the minutes of a phone call regarding the Dear Doctor letter.

Okay. Go ahead with what you were saying.

MR. NORTH: And here are those minutes if the Court

11:37:29 needs them. But that was the context in which I referenced

11:37:32 the Dear Doctor letter, was this phone call.

I had at no time tendered or presented the Dear Doctor letter itself, and I don't believe I asked her any opinion as to the adequacy. Merely the fact there had been

11:37:44 communication.

That particular document, the Court has ordered the second sentence out, which we will do, of course, and there are also references to death in that that need to be redacted, which is why I didn't display the second page.

11:37:59 THE COURT: Finish your response to what Mr. Lopez said.

MR. NORTH: Well, that's the main thing. I don't think I opened the door as to the adequacy of the Dear Doctor letter.

11:38:09 As far as predicate devices, I think that was essentially --

THE COURT: I'm going to forget where I am. Let's talk about that second, your second point, Mr. Lopez.

On the first one, which is the Dear Doctor letter, my

11:38:26 notes, which are pretty thorough, show that this was after you tried to introduce the chronology and I didn't let you bring it in.

She testified that Bard approached the FDA to discuss a letter to be provided to doctors, the FDA provided feedback

11:38:48 on it. And also on plans to engage with the physician

11:38:53 community. I assume that meant focus group type events.

The Dear Colleague letter was sent by Bard to doctors. Bard submitted a draft to the FDA. The FDA provided feedback and Bard made the suggested changes and sent out the

11:39:10 letter.

Bard sent a second letter to doctors after consulting with the FDA.

Then you introduced the minutes of a phone call regarding what Bard was seeing with the Recovery and the plan

11:39:25 to provide a Dear Doctor letter. The minutes were authored by the FDA, obtained through a FOIA request.

Bard asked if changes to I think the doctor letter would constitute a change in labeling that required a new 510(k). FDA provided input on the letter. FDA agreed that

11:39:54 the bolded statement would address the issue but that Bard continued -- needed to continue diligently monitoring.

I don't know what the bolded statement is.

MR. NORTH: The IFU, Your Honor. Statement about risk/benefit that we continued to express on the second page.

11:40:14 THE COURT: Okay.

But I guess my question for you, Mr. North, is, it seems to me the clear import of all of that testimony is that with respect to complications Bard was seeing in the Recovery filter, it went to the FDA, proposed what it would communicate

11:40:35 to the doctors, the FDA reviewed it and made suggestions.

11:40:40 Bard adopted the suggestions and sent out the letter.

The whole implication is the FDA approved what Bard was saying in the Dear Doctor letter about Recovery filter complications. Isn't that the point?

11:40:56 MR. NORTH: I don't think the point is approved, but they did review it, yes.

THE COURT: But, I mean, what you want --

MR. NORTH: -- distinction --

THE COURT: What you want the jury to come away with

11:41:05 is that whatever Bard said in the letters to doctors about Recovery filter complications had been run by the FDA and, if not expressly approved, they hadn't had any objection, and, in fact, you incorporated changes they made. So they were sort of a party in putting together this communication to

11:41:22 doctors.

Do you disagree with that?

MR. NORTH: No. Not at all.

My intent was to show the agency's knowledge about what Bard was doing and the fact that there was this dialogue

11:41:34 going on. Not so much that they approved it. But I understand the Court's implication.

THE COURT: So here's the question: If the plaintiff believes that Bard was not forthcoming in the letter to the doctors about deaths caused or related to the

11:41:56 Recovery filter, why isn't that relevant in light of the fact

11:42:02 that Bard has in effect said this filter had the blessing of the FDA and talked about Recovery filter complications to doctors?

MR. LOPEZ: Including death.

11:42:17 MR. NORTH: Your Honor, he's already brought out, as the Court ruled earlier, he can testify -- he can bring out evidence that this device can, as a complication, lead to death. He has done that. I mean, these last few questions with that firmly in the record, and many other people have.

11:42:36 I don't see how the mention of a Dear Doctor letter or a Dear Colleague letter, without going into the specifics, opens the door to this avalanche of materials as to the details.

It's then going to require me to come in and we're 11:42:54 going to start litigating the same subsidiary peripheral issue because all the documents are replete, FDA internal documents, with their knowledge of these deaths. And so then we're going to get into all of this and it's going to be a trial within a trial.

11:43:11 It is marginal relevance as to the details. We were talking about the fact of a letter. And that evidence is in. The FDA reviewed that letter. But the details of what the complications were, he's already established that it included death. To get into each single event, we can show the FDA 11:43:34 knew of each single event.

11:43:35 THE COURT: Does the Dear Doctor letter say anything about death?

MR. NORTH: Yes.

THE COURT: What does it say about death?

11:43:40 MR. NORTH: I'm going to have to go get it. I did not have it to use with her, the Dear Colleague letter.

There were two, a Dear Doctor and Dear Colleague. The Dear Colleague references death.

THE COURT: How much longer do you have on cross?

11:44:00 MR. LOPEZ: I just got my five-minute warning, so -- it's going to be longer than that, though.

THE COURT: And how much redirect are you going to have?

MR. NORTH: Depends on the Court's ruling. Right

11:44:10 now I have no --

THE COURT: We've got 15 minutes before the noon hour. I'm just conscious -- I think I need to look at the Dear Doctor letter and think about this issue further.

The question on my mind is whether -- well, I think

11:44:26 the jury has clearly been given the impression that the Dear Doctor letter provided, in effect, an FDA-approved description of the Recovery filter risks. And if the plaintiff has a basis for saying, no, it didn't, there were risks that weren't adequately communicated to the doctors, I think that's fair

11:44:46 game.

But I can't assess that -- I mean, I know there hasn't been -- the Dear Doctor letter hasn't been admitted.

Are you going to try to put it in?

MR. LOPEZ: No. I mean probably not. But I don't know. Depends where this goes, Judge.

THE COURT: What I'm wrestling with is whether -- I think it's fair for the plaintiff to present evidence that the Dear Doctor letter was not an adequate description of the risks, if the plaintiff can do so. I can't assess that without having a sense for what's in the letter, whether it does or does not mention deaths. If so, how it mentions deaths. So I need to look at it. And I don't want to keep the jury waiting while we do that.

MR. LOPEZ: Can I make one more -- there's a whole separate layer that's equal to that, which is continuing to tell the jury through this witness how transparent they were with FDA about those deaths and quality of those deaths and internal analysis about those deaths and recommendations Dr. Ciavarella was making about those deaths and the report from the HHE which showed there was an increased risk of almost five times amount of deaths than any other device on the market, and all of those things were consistent with their bench testing. I mean, we can't -- all of that.

THE COURT: I understand what you're saying, Mr. Lopez.

11:46:02 I continue to be of the view that in an Eclipse case, that stuff happening in 2004 and 2005 is marginally relevant for all of the reasons I stated in my prior orders. So I'm not persuaded that your inability to go through that in detail 11:46:19 is something that over -- that makes my Rule 403 ruling incorrect.

What I'm really focused on here is the evidence that's now been presented to this jury about the Dear Doctor letter and the FDA's involvement. I think that's fair game 11:46:34 because that's what the defendants have interjected. So that's my focus.

I don't want to turn this into the trial -- a trial about what was or was not told to the FDA in 2004, 2005 because I view that as marginally relevant.

11:46:47 I know your hand's up. We've got to move along, and I'm going to use the one-lawyer rule here.

MR. O'CONNOR: Still have an issue from yesterday that I raised with you that does implicate the Eclipse. That's what I wanted to bring up.

11:47:00 THE COURT: What issue is that?

MR. O'CONNOR: The way they used the Eclipse IFU and made it appear any mention of death in the obese, morbidly obese, patients, they implied that was something --

THE COURT: We've left that for the question they 11:47:15 were going to get an answer to of whether there's evidence of

morbidly obese deaths from other filters. So that's a different issue.

MR. O'CONNOR: Except I just wanted you to -- I just wanted to make the point that does apply to the Eclipse. It was Eclipse.

THE COURT: Okay. I understand.

(Bench conference concludes.)

THE COURT: Ladies and gentlemen, thank you. Sorry to stay so long.

Let's continue, Mr. Lopez, on your next subject, and I'll work further on this issue over the lunch hour so we're not keeping the jury waiting.

MR. LOPEZ: Thank you, Your Honor.

BY MR. LOPEZ:

Q You would agree that labeling needs to include information that patients and their doctors need in order to make decisions about whether or not to use the product; right?

A I would say in general that's a reasonable statement, yes.

Q And the warning needs to be specific to the safety profile of the company's device, not just the safety profile of everyone's device. If there's something uniquely different about the risk profile of a Bard filter, the warning needs to make sure a doctor knows that there's something different about maybe fractures, for example, in a Bard filter versus maybe fractures in a Simon Nitinol filter. Don't you agree

11:48:45 that doctors should know about those differences?
A So I certainly think if there's a failure mode or complication that's different from -- of a particular company's device that that information should be disclosed in
11:48:58 the labeling, so that not all device labeling is the same.
Q Now, what is a company's obligation when it knows it's selling a device that they know would never have gotten cleared through a 510(k) process had FDA had the clinical data that the company now has from marketing it?
11:49:26 A I'm not -- I mean, that's a question that there's so many "it depends" in that I'm not sure I can give you a general answer to it.
MR. LOPEZ: Gay, can I -- this is her June 2014 deposition, page 168, beginning line 17.
11:49:50 BY MR. LOPEZ:
Q See there? I'm going to read from line 17.
MR. LOPEZ: Gay, when I'm done, the answer goes on to the next page.
BY MR. LOPEZ:
11:50:00 Q I can read it -- oh. Could you see that okay, Dr. Tillman?
A Yeah, I could see the question. It was the same one you just asked me.
Q The question is:
11:50:08 "Really, what is the company's obligation

when it knows that it's selling a device that they knew would never have gotten cleared through a 510(k) process had FDA had the clinical data it now has that it's marketing?"

"Answer: Once again, there are certainly postmarket regulatory controls, including corrections and removals, and the fact that, as you mentioned, it's illegal to sell an adulterated device. So if the company becomes aware -- aware that its device is adulterated for whatever reason, if it's not meeting specifications or performing to meet user needs and intended uses, then the company has an obligation to remove that product from the market."

That was your answer in 2014; correct?

A Yeah. I think that's a good answer.

Q Dr. Tillman, would you expect that a company determines, based on risk analysis, that the product fell into the unacceptable category that they would take some kind of action, including recall?

A So what do you mean by "unacceptable category"?

MR. LOPEZ: Could I have her deposition, Gay. Same one, August -- I'm sorry, this one's June 12, 2014. 269.

Right to there, line 8.

11:51:50 BY MR. LOPEZ:

Q Your deposition was taken also in 2017; correct?

A Yes. I've been deposed twice in this matter, I think.

Q In fact, I gave you a copy of the 2014 deposition that

11:52:02 we're reading now at that deposition. Do you remember that?

A I don't remember if you gave me a copy, but I certainly have copies of both depositions.

Q And you told me you didn't have any changes to make to the 2014 deposition when I took your deposition in 2017; correct?

11:52:16 A Yeah. I looked at these since then and I don't have any changes to make to these.

Q Okay. At line 8 you stated:

"I would expect if a company determines, based on risk analysis, that the product fell into

11:52:28 the unacceptable category that they would take some kind of action."

Then I asked: "Including recall?"

And you said: "I think they need to take some kind of action to correct the unacceptable

11:52:43 risk. That could be recall. It could be a safety communication to providers. I mean there's a bunch of different things they could do, but I would expect they need to do something."

That was your testimony in 2014 that you agreed --

11:52:54 that you agreed you were not going to change when I took your

deposition in 2017; correct?

A Yes. So the reason I was a little bit more uncertain --

MR. LOPEZ: Your Honor, there's no question pending.

THE WITNESS: You asked me "Correct?"

BY MR. LOPEZ:

Q Whether or not that was your testimony.

A So that -- what you just read was my testimony.

Q Okay.

MR. LOPEZ: And can we look at 271/7, Gay, please. Put that up as well.

BY MR. LOPEZ:

Q Page 271, line 7, you stated under oath:

"So I believe that if a company becomes aware that a device presents an unreasonable risk, that they need to take appropriate action and communicate appropriately to their stakeholders. So in general" --

MR. NORTH: I'm sorry. Objection. Improper impeachment.

THE COURT: I don't think you asked her a question that this is inconsistent with.

MR. LOPEZ: Well, I don't know, I said something that prompted me to do this and I can't remember what it was. Okay.

11:53:55 BY MR. LOPEZ:

Q Let me ask you this --

THE COURT: Let's just have you go on with your question along this line and you can use it if it becomes --

11:54:01 BY MR. LOPEZ:

Q So, ma'am, do you believe that if a company becomes aware that a device presents an unreasonable risk that they need to take appropriate action and communicate appropriately to their stakeholders? Yes or no?

11:54:17 A So I can't answer that question yes or no because since the time this deposition was taken I've become aware of a Bard document where there was a formal definition of "unreasonable risk," which I believe may be different than just the common understanding of what that means.

11:54:34 So I agree that the statement I made here, if we're just talking about unreasonable risk in the commonly accepted interpretation of the term, I agree, the statements I made, that's what those are based on.

So I would agree that if we're talking about

11:54:51 unreasonable risk, then, yes, companies need to take action.

Q Dr. Tillman, do you agree that it's important for medical device manufacturers to share relevant postmarket safety information with health care providers and patients, and that they have the primary responsibility, meaning the company that

11:55:12 sells and profits from the device, for insuring the safety and

effectiveness of the device?

A So I agree the companies have primary responsibility for ensuring the safety and effectiveness of the device.

Q And do you also agree that it's not appropriate for a company to use a device as a predicate device if the device is either misbranded or adulterated?

A So I believe that in general a device that's been found to be misbranded or adulterated should not be used as a predicate device.

Q And isn't it also -- I'm sorry, did I interrupt you?

A No.

Q Is it also true that FDA does not regulate advertising and promotional materials for medical devices the way it does for drugs so you're convinced that this is necessarily a piece -- I'm sorry. Let me start that over.

Do you agree that FDA does not regulate advertising and promotional materials for medical devices the way it does for drugs?

A I would say that is true, yes.

Q If a company knows that it has design deficiencies, do you agree that not only do they need to tell doctors, but they need to do something to correct the design deficiency?

A So I think that if a company is aware that a device is not performing the way that they expected it to in the market or that if it's not meeting specifications, then, yes, they need

11:56:44 to do something is to address that matter.

Q If they have design deficiencies, would you agree they ought to stop selling it until they fix it?

A So I think it depends what you mean by design

11:56:57 deficiencies.

Q Well, in other words, they've identified that it's having complications, known complications, but because of the design of the device it's contributing to or causing those complications like migration and tilting and perforation and

11:57:14 fractures. They know it's related to a design. They know what they need to do to fix it. Shouldn't they stop selling it and fix it?

A So those adverse events you mentioned are known complications associated with IVC filters. Just because a

11:57:31 device has those complications doesn't mean it has a design deficiency.

Q Ma'am, my hypothetical included the company internally recognizing they need to make the design changes to minimize or eliminate that complication. You took that out.

11:57:47 So let me just ask it this way. In fact, why don't we show you your deposition. It was taken in August of 2017 at page 189.

MR. NORTH: Your Honor, again, objection. I'm not sure there's a question or answer to be impeached.

11:58:04 THE COURT: Overruled.

BY MR. LOPEZ:

Q Page 189 line 7:

"Well, I didn't ask you whether you agreed with me or not. I want you to -- I'm just asking you if a company knew it had design deficiencies in their device that was causing or contributing to migrations of the device with a clot in it to the heart and causing death, don't you think physicians would have wanted to know that?"

"I can't answer that question because I think if a company knows it has, quote, design deficiencies, then not only is that something physicians ought to know, but the company actually needs to do something about it."

"Question: They ought to stop selling it?"

"Answer: If they have design deficiencies."

That's what you testified to less than a year ago; right?

A And I'm not disagreeing with what I said then. My point simply is I think you have to be careful about what is a design deficiency versus what is just a device performing in a way that it -- where a device is known to have certain adverse events. If a device has that event, it doesn't mean there's a

design deficiency.

Q Would you agree with this simple concept --

THE COURT: Actually, Mr. Lopez, we're at the noon hour so we're going to break at this point.

Ladies and gentlemen, we will resume at 1 o'clock. We'll excuse you at this time.

(The jury exited the courtroom at 11:59.)

THE COURT: All right. Counsel, do you have a copy of the Dear Colleague letter that was discussed?

MR. NORTH: That is both of the letters, Your Honor. Dear Colleague and Dear Doctor.

MR. O'CONNOR: Can we see what you've shown him.

THE COURT: Okay. What you've handed me, it looks like, are Exhibits 5915 and 5001. Is that right?

MR. NORTH: Yes.

THE COURT: And can you point to me -- point me to where in the letters it talks about death. And if you can't, I'll read them. I don't want --

MR. NORTH: May 11, 2005, Exhibit 5915, the third sentence: "Over the past two years we have received adverse event reports of filter migration, some being associated with medical intervention and/or death."

MR. LOPEZ: Next sentence too, Your Honor.

MR. NORTH: That's the mention of death in that one.

Your Honor, the Dear Doctor letter is merely advising

about changes to the IFU which actually added that bolded statement on page 2 of 2. This is Exhibit 5001. In advising of the changes to the IFU it added that "All of the above complications have been associated with serious adverse events such as medical intervention and/or death."

And that was the bolded language that the FDA was talking about in that Exhibit 6075.

THE COURT: Okay.

All right. What I want to do, Counsel, in light of our sidebar, is read these letters. I'm going to go back and look at the transcript again and think about the issues that have been raised so that I can give you a ruling on the question.

MR. LOPEZ: I need 30 seconds too, Judge.

THE COURT: For a new issue?

MR. LOPEZ: On this issue.

THE COURT: What were you going to say, Mr. North?

MR. NORTH: I was going to say, Your Honor, I have some materials about morbidly obese deaths in other -- with other manufacturers. I was going to give a copy to the Court and one to the plaintiffs, I will tell you it's a lot to wade through, if and when the Court's ready --

THE COURT: Tell me what's in it.

MR. NORTH: There are two different --

THE COURT: Have you given the materials to the

plaintiff's counsel?

MR. NORTH: Let me. Here.

Two different MAUDE reports involving other manufacturers and death, migration deaths, in morbidly obese people. There's also a major medical article which is a case report of a migration death with a competitive filter. And most important, there's an overview article of approximately 70 or 80, I think, reports in the medical literature of migrations of filters to the heart, and it notes importantly on page 880 of the article that in eight of the reported cases involving all sorts of manufacturers the cause for filter migration was attributed to a mega cava, which is a huge cava. Implying these are morbidly obese patients because of the very large, greater than 28 millimeter in diameter, cavas.

THE COURT: Okay. I don't know that I'm going to have time over the lunch hour to look at that, but I understand now what materials you're giving to me.

You wanted to say something, Mr. Lopez, for 30 seconds.

MR. LOPEZ: Yes. The next two sentences are important too because --

THE COURT: Of what?

MR. LOPEZ: Of this letter, about it comparing to the SRI guidelines. I can tell you I've got testimony from her at her deposition where she agrees that is inappropriate

comparison because it does not describe --

THE COURT: That's not the issue. This letter isn't in front of the jury and so what's in the letter and whether you can impeach it isn't the question.

The letter I'm going -- the issue I'm going to focus on is whether or not what's been said to the jury about the FDA's involvement with this letter has opened the door for you to bring out some information about death. To do that I wanted to understand what the letter is. But I'm not looking through the letter asking is there something in here the plaintiff can disagree with, because this isn't in evidence.

MR. LOPEZ: Well, he certainly opened the door for me to admit this letter when he talked about it.

THE COURT: If you decide to admit it, that will be your choice. That, to me, doesn't open any door if you put it in. The question is whether their evidence opened the door for you.

MR. LOPEZ: It's kind of a door -- I made it wider, but he kind of took it -- made it so I --

THE COURT: And you may choose to put it in. That's fine. But if you put it in, I'm not going to say your putting it in opens a further door for you.

MR. LOPEZ: No, I understand, but I've got to be able to show the jury he misrepresented its transparency to FDA, its transparency to doctors like the impression he was

leaving the jury. I've got to be able to tell the jury, no, this was an opportunity for them to come clean about a lot of stuff and they didn't.

THE COURT: Again, what I said at sidebar is I'm not revisiting the whole 403 issue. I continue to believe that cephalad migration death evidence in the Recovery filter is marginally relevant in this Eclipse case. So I'm not going to change that ruling.

What I am trying to decide is whether what the defendants have presented, in fairness, should allow you to put in something about it. That's what I'll work on over the lunch hour.

MR. LOPEZ: Thank you, Your Honor. I just don't want them to take unfair advantage of that ruling. I think maybe they have.

THE COURT: I understand you don't. I don't want them to, either.

Thank you all.

Oh, I'll give you your time. Do you need your times now or is the end of the day okay?

MR. LOPEZ: I can only deal with that once a day, Judge.

THE COURT: Okay.

MR. LOPEZ: We're probably going to need it. We're going to need it.

12:06:07 THE COURT: Now? All right. Give me just a minute.

MR. LOPEZ: You're not going to count that sidebar against me, are you?

THE COURT: I'm giving seven minutes of that sidebar 12:06:22 to defendants. I split it evenly. You're keeping the jury waiting, so that's what I do. If a sidebar is entirely unwarranted, in my view, I leave it on the party who requested it. If it's a genuine debate, I split it. That's what I'm doing with this sidebar.

12:07:28 All right. As of the lunch hour plaintiff has used 22 hours and 53 minutes. Defendant has used nine hours and 42 minutes.

We'll see you at 1 o'clock.

MR. LOPEZ: Thank you, Your Honor.

12:07:40 (End of a.m. session transcript.)

* * * * *

C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 24th day of May, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter